

I n t e r i m R e p o r t

PRESIDENTIAL
ADVISORY
COMMITTEE ON
GULF WAR
VETERANS' ILLNESSES



PRESIDENTIAL ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES

Joyce C. Lashof, M.D., Committee Chair

Former Dean and Professor Emerita

School of Public Health

University of California, Berkeley

Berkeley, CA

John Baldeschwieler, Ph.D.

Professor of Chemistry

California Institute of Technology

Pasadena, CA

Arthur L. Caplan, Ph.D.

Director, Center for Bioethics and

Trustee Professor of Bioethics

University of Pennsylvania

Philadelphia, PA

Admiral Donald Custis, M.D. (Ret.)

Senior Medical Advisor

Health Policy Department

Paralyzed Veterans of America

Washington, DC

Major Thomas P. Cross¹

Sales Engineer

Bell Industries

Meriden, CT

David M. Hamburg, M.D.

President

Carnegie Corporation of New York

New York, NY

James A. Johnson

Chairman and Chief Executive Officer

Federal National Mortgage Association

Washington, DC

Major Marguerite Knox, R.N.C., M.N., C.C.R.N.

Clinical Assistant Professor

College of Nursing

University of South Carolina

Columbia, SC

Philip J. Landrigan, M.D.

Ethel H. Wise Professor and Chairman

Department of Community Medicine

Mount Sinai School of Medicine

New York, NY

Elaine L. Larson, R.N., Ph.D.

Dean

School of Nursing

Georgetown University

Washington, DC

Rolando Rios

Attorney

San Antonio, TX

Andrea Kidd Taylor, Dr.PH.

Occupational Health Consultant

Health and Safety Department

United Auto Workers

Detroit, MI

General Frederick M. Franks, Jr. (Ret.)²

Alexandria, VA

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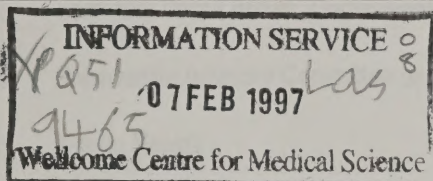
¹Appointed December 1, 1995

²Resigned October 27, 1995



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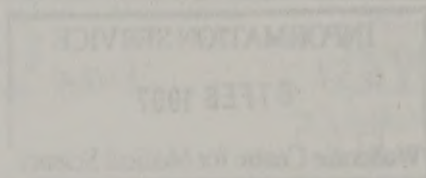


Presidential Advisory Committee on Gulf War Veterans' Illnesses

Interim Report

February 1996

U.S. GOVERNMENT PRINTING OFFICE: 1996



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Recommended citation: *Presidential Advisory Committee on Gulf War Veterans' Illnesses: Interim Report* (Washington, DC: U.S. Government Printing Office, February 1996).



Presidential Advisory Committee on Gulf War Veterans' Illnesses

Chair

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Major Marguerite Knox, M.N.

Philip Landrigan, M.D.

Elaine L. Larson, Ph.D.

Rolando Rios, Esq.

Andrea Kidd Taylor, Dr.P.H.

Executive Director

Robyn Y. Nishimi

Deputy Director/Counsel

Holly L. Gwin

MEMORANDUM

TO: Secretary William Perry, Department of Defense
Secretary Donna Shalala, Department of Health and Human Services
Secretary Jesse Brown, Department of Veterans Affairs

FR: Presidential Advisory Committee on Gulf War Veterans' Illnesses

RE: Interim Report

DA: February 15, 1996

On behalf of the Presidential Advisory Committee on Gulf War Veterans' Illnesses, I am pleased to transmit our Interim Report.

Joyce C. Lashof, M.D.
Committee Chair

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Executive Summary

President Clinton established the Presidential Advisory Committee on Gulf War Veterans' Illnesses to ensure an independent, open, and comprehensive examination of health concerns related to Gulf War service. This 12-member panel, made up of veterans, scientists, health care professionals, and policy experts, will review the full range of relevant activities, including: research, coordinating efforts, medical treatment, outreach, reviews conducted by other governmental and nongovernmental bodies, risk factors, and chemical and biological weapons.

As mandated by Executive Order 12961, we are delivering our interim report to the President, through the Secretaries of Defense, Health and Human Services, and Veterans Affairs, six months after our initial meeting (held on August 14-15, 1995). Our final report will be delivered no later than December 31, 1996.

This interim report includes four chapters addressing specific elements of the Committee's charter: outreach, medical and clinical issues, research, and chemical and biological weapons. The final chapter describes the Committee's work plan for the next 10 months. Within each chapter, the Committee presents its analytical approach; describes background material uncovered through testimony, document review, and interviews; and makes findings based on investigations to date. Recommendations we believe can improve the government's response to the broad array of issues encompassing Gulf War veterans' illnesses follow.

OUTREACH

The Committee found the Department of Defense (DOD) and the Department of Veterans Affairs (VA) have used a number of progressive techniques—from establishing telephone hotlines for the health care programs that serve veterans to posting declassified documents on the Internet—to educate veterans and other citizens concerned about Gulf War veterans' illnesses. Neither department, however, has adopted performance measures sophisticated enough to evaluate the success of these programs. Our investigation revealed some relatively simple ways for the departments to receive feedback on the utility of various outreach programs and a critical need to present information to veterans more clearly.

Presidential Advisory Committee

- Operators at the DOD Medical Registry Hotline, DOD Incident Reporting Line, and VA Helpline should be instructed to ask "How did you find out about this number?" as a method of qualitatively measuring the success of the different methods for publicizing the numbers.
- In the next Comprehensive Clinical Evaluation Program end-of-evaluation questionnaire, which participants answer when the initial evaluation is completed, DOD should include a question about satisfaction with the referral provided by the Persian Gulf Medical Registry Hotline.
- DOD and VA should utilize more refined performance measures to determine how well outreach services are reaching concerned parties. Caller volume data are not adequate.
- To assist the general public in interpreting the declassified intelligence documents on GulfLINK [a DOD site on the World Wide Web], DOD should prepare a user's guide. This guide should explain in general terms the various sources of intelligence information, how they may differ in quality and reliability, and how intelligence analysts compile and evaluate reports from a variety of sources in the field to obtain corroboration before preparing a final assessment. This guide should be featured prominently on the GulfLINK home page.
- In its outreach campaign, VA should forego use of the term "priority care." VA should state clearly that Gulf War veterans are entitled to receive the Persian Gulf Health Registry examination free of charge, including any diagnostic testing found to be medically necessary and counseling regarding findings.
- VA should make its broadcast public service announcements (PSAs) about the toll-free Helpline more explicit. The PSAs should include brief explanations of the purpose of the Helpline and the referral process for the Persian Gulf Health Registry.
- Future conflicts are likely to generate controversial and unexplained health concerns, and DOD and VA should anticipate the need and plan for outreach services and implement them expeditiously.

MEDICAL AND CLINICAL ISSUES

For this interim report, the Committee focused on medical treatment issues that surfaced during the deployment and demobilization of troops. We found DOD's policies and procedures were not adequate in all cases to prevent service members with preexisting conditions from being deployed or to identify health problems extant at the time of demobilization; these conditions could have contributed to some current health concerns.

The Committee believes DOD and the Food and Drug Administration (FDA) deliberated carefully before enabling, through rulemaking, DOD to require troops to take pyridostigmine bromide (PB) and botulinum toxoid (BT) vaccine as antidotes to possible chemical and biological warfare (CBW) agents without FDA approval of the products for that purpose. Yet we find FDA has failed, in the five years since the Gulf War, to devise better long-

term methods governing military use of drugs and vaccines for CBW defense. We also find DOD's inability to produce the records of who received PB or BT indicative of much need for wholesale improvement in the government's performance on medical recordkeeping during military engagements.

- *DOD should regularly review and update the policies and procedures that govern the pre-, during, and postdeployment medical assessment of the Ready Reserve to ensure they are current and adequate.*
- *DOD should establish a quality assurance program to ensure compliance with pre-, during, and postdeployment medical assessment policies.*
- *Prior to any deployment, DOD should undertake a thorough health assessment of a large sample of troops to enable better postdeployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely postdeployment followup.*
- *Given that FDA's interim rule [permitting waiver of informed consent for use of unapproved products in a military exigency] is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare.*
- *If FDA decides to reissue the interim final rule as final, it should first issue a Notice of Proposed Rule Making. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long term followup of individuals who receive investigational products; review by an institutional review board (IRB) outside of DOD; and additional procedures to enhance understanding, oversight, and accountability. The Committee, at this time, withholds judgment on the adequacy of the current interim final rule.*
- *DOD should assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data (including classified information, if and when it is needed) in the field. DOD and VA should adopt standardized recordkeeping to ensure continuity.*

RESEARCH

The Committee found most of the studies sponsored by DOD, VA, and the Department of Health and Human Services (DHHS) are well designed and appropriate to determine if Gulf War veterans have mortality, symp-

toms, or diseases that might be attributable to service in the Gulf War. However, we believe inadequate response to scientific peer review, disregard for the importance of allocating scarce research dollars to the best designed studies, and inattention to the need to communicate effectively with veteran participants are undermining the effectiveness of the government's research efforts. The lack of data about exposure to various risk factors (e.g., oil fire smoke or infectious diseases) also hampers research. Though DOD is attempting to recreate certain exposure scenarios with the Persian Gulf Registry of Unit Locations, we recommend heightened efforts to collect exposure data in future conflicts.

- *All epidemiologic studies aimed at Gulf War veterans' health issues should incorporate external scientific review and ongoing interaction with appropriate outside experts throughout the study process, from study design through analysis of results.*
- *The Persian Gulf Veterans Coordinating Board should play an active role in allocating the limited resources available for research on Gulf War veterans' illnesses. The Research Working Group of the Coordinating Board should monitor the findings and recommendations of scientific peer review committees. If scientific reviews draw into question the usefulness of particular studies to the overall research strategy, the Research Working Group should, via the Coordinating Board, recommend appropriate actions to the Secretaries of the three departments involved.*
- *DOD, DHHS, and VA should recommend their principal investigators use public advisory committees in designing and executing epidemiologic studies of Gulf War veterans' illnesses.*
- *For those questions that are common to different [epidemiologic] surveys, coordination between principal investigators and survey design experts should take place to arrive at common wording. The Persian Gulf Veterans Coordinating Board's Research Working Group should take responsibility for this coordination.*
- *The Persian Gulf Registry of Unit Locations should be made available to qualified government and private researchers as quickly as possible, within the constraints of confidentiality.*
- *DOD should make reasonable and practical efforts to collect and record better troop exposure data during future conflicts and to make those data available as quickly as possible to health care researchers.*

CHEMICAL AND BIOLOGICAL WEAPONS

The work of the United Nations Special Commission on Iraq (UNSCOM) provides a more definitive picture of Iraq's advanced CBW capabilities than was available at the time of the Gulf War and underscores the considerable uncertainty regarding Iraq's intentions to use CBW agents against American and coalition troops. The Committee believes the decisions of

DOD and the Central Intelligence Agency (CIA) to reopen their investigations of CBW in the Gulf War are positive steps and urges DOD and CIA to draw fully on their resources to answer some of the war's most controversial questions; we will monitor their progress carefully. In addition, we find improved technology to detect the presence of CBW agents would improve the health care surveillance of troops involved in future conflicts.

- *CIA and DOD should coordinate their analyses to ensure a comprehensive review of the complete record of the Gulf War. Each agency should make full and prompt disclosure of all findings.*
- *DOD should devote more attention to monitoring low-level (subacute) exposures to chemical warfare (CW) agents. One possible basis for such a system is the automated air-sampling system developed by the U.S. Army Edgewood Research, Development and Engineering Center for UNSCOM, which is using it to monitor emissions from Iraqi chemical plants. Another approach might be to modify the detection system the U.S. Army uses to monitor for leaks at chemical weapons storage depots.*
- *DOD should continue to invest in the development of a biological point detector/alarm system that can detect and identify biological warfare (BW) agent aerosols rapidly enough to enable troops to take protective measures before being exposed.*

CONCLUSION

The Committee adopted the strategy of investigating and analyzing for the interim report those key questions raised by the charter we believed could be answered in the near-term. Toward this end, the Committee received testimony from the public and government officials and reviewed scores of reports related to Gulf War veterans' illnesses. This document reports the Committee's evaluations to date and makes findings and recommendations in each of the major areas of our mandate, but our work is by no means complete.

Securing a healthy future for Gulf War veterans is of paramount importance to President Clinton. We promise our full dedication to his charge.

Chapter 1

Introduction

This independent Advisory Committee will help ensure that we are doing everything possible to determine the causes of the illnesses being reported by Gulf War veterans and to provide effective medical care to those who are ill.

*– President Clinton
May 26, 1995*

On August 2, 1990, Iraqi forces invaded Kuwait. Five days later, U.S. troops began deployment to the Persian Gulf region as part of Operation Desert Shield, which became Operation Desert Storm when Coalition air forces began the attack on Iraqi targets on January 17, 1991. On February 24, 1991, the ground war began when the U.S. military and other coalition partners attacked Iraqi troops in southern Iraq and Kuwait. One hundred hours later—on February 28, 1991—the fighting ceased.

In all, approximately 697,000 men and women of the U.S. military (including members of the National Guard and Reserves) served in Southwest Asia during Operations Desert Storm/Desert Shield. Casualties were unexpectedly low. During the conflict, 145 service members died in combat; nonhostile actions claimed 225 lives.

By June 13, 1991, the last U.S. service members who participated in the ground war returned to the United States. Victory brought no peace for some Gulf War veterans, however, as they began to report debilitating, chronic illnesses with a variety of symptoms, including fatigue, joint pain, headache, rash/dermatitis, and memory loss. In some cases, physicians have been unable to pinpoint a clear diagnosis.

Realizing the debt owed to individuals who served in the Gulf War and determined to learn from our country's experience with veterans' health issues, the Administration and Congress undertook several initiatives to address the health of U.S. troops that had served in the Gulf War. President Clinton took the additional step on May 26, 1995, of issuing Executive Order 12961 to establish the Presidential Advisory Committee on Gulf War Veter-

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ans' Illnesses (Appendix A) to ensure an independent, open, and comprehensive examination of health concerns related to Gulf War service.

THE ADVISORY COMMITTEE

The Committee has a long-term mission to analyze and review, in an interdisciplinary, cross-agency fashion, the broad array of topics associated with Gulf War veterans' illnesses. The Committee is concerned that some veterans suffer from real, debilitating illnesses linked to service in the Gulf War. A 12-member panel made up of veterans, scientists, health care professionals, and policy experts, we have been charged (Appendix B) to review the full range of government activities relating to Gulf War veterans' illnesses, including:

- research,
- coordinating efforts,
- medical treatment,
- outreach,
- reviews by other governmental and nongovernmental bodies,
- risk factors, and
- chemical and biological weapons.

The Committee has been directed to issue its findings and recommendations to the President through the Secretaries of Defense, Health and Human Services, and Veterans Affairs in a final report to be delivered no later than December 31, 1996. As mandated by the Executive Order, this document, the Committee's interim report, is being delivered six months following the first meeting, which was held in Washington, DC on August 14-15, 1995.

Relationship to Other Efforts to Address Gulf War Veterans' Illnesses

All of us share President Clinton's pledge to "leave no stone unturned" in the effort to ensure the government's response to Gulf War veterans is compassionate and fair. While this Committee is the first group broadly charged to analyze Gulf War veterans' illnesses, ours is not the first, or only, effort by the Administration to address health concerns stemming from service in the Kuwaiti Theater of Operations (Figure 1). As required by the charter, the Committee has reviewed the work of groups that have issued reports.^{*} We have assessed (or will assess in the final report) whether those groups' recommendations have been implemented or whether findings and/or recommendations merit updating in light of newly available information.

With respect to other reviews that are ongoing (e.g., those of the IOM and the Persian Gulf Expert Scientific Committee of the Department of Vet-

The Committee has a long-term mission to analyze and review, in an interdisciplinary, cross-agency fashion, the broad array of topics associated with Gulf War veterans' illnesses.

^{*}For example, the Office of Technology Assessment,^{1,2} the Defense Science Board (DSB) Task Force on Persian Gulf War Effects,³ the National Institutes of Health (NIH) Technology Assessment Workshop on the Persian Gulf Experience and Health,⁴ the Institute of Medicine (IOM) Committee on the Department of Defense Persian Gulf Syndrome Comprehensive Clinical Evaluation Program,⁵ IOM's Committee to Review the Health Consequences of Service During the Persian Gulf War,⁶ and the General Accounting Office.^{7,8}

erans Affairs (VA)), the Committee has availed itself of the expertise and experiences of these bodies to avoid unnecessary duplication of effort. We intend to continue this consultation as we develop the final report.

The Committee's Process

The President has made clear his belief that only an open government is a responsive government. The Committee operates under the Federal Advisory Committee Act, conducting its business in open public meetings and providing the opportunity for comment from any interested member of the public at each meeting. Individuals who wish to submit written material for the Committee's consideration may do so at any time.

The Committee's deliberations are supported by the work of a full-time staff and several consultants (Appendix C). To date, the Committee has held four full Committee meetings and three focused panel meetings—clinical care, epidemiologic research, and ethical considerations of the use of unapproved drugs and vaccines—around the country (Appendix D). Currently, we plan to convene full Committee meetings approximately bimonthly through fall 1996, as well as to hold additional panel meetings. All meetings are announced in the *Federal Register*, and each meeting will provide an opportunity for public comment.

FOCUS OF THIS INTERIM REPORT

The Committee adopted the strategy of investigating and analyzing for the interim report those key questions raised by the charter we believed could be answered in the near-term. Toward this end, the Committee has received testimony from the public and government officials and reviewed scores of reports related to Gulf War veterans' illnesses. This document reports the Committee's evaluations to date. We make findings and recommendations in each of the major areas of our mandate, but our work is by no means complete.

For the interim report, the Committee organized the seven elements of the charter into four broad chapters: outreach, medical and clinical issues, research, and chemical and biological weapons. The mandate to review the government's coordinating efforts and to assess the implementation of recommendations from past reports is addressed within the context of the subject matter of the chapters, as applicable. We discuss health risks in the context of either research or clinical issues, as appropriate. Within each chapter, the Committee presents its analytical approach; describes background material it has uncovered through testimony, document review, and interviews; makes findings based on its investigations; and offers recommendations we believe can improve the government's response to the broad array of issues encompassing Gulf War veterans' illnesses.

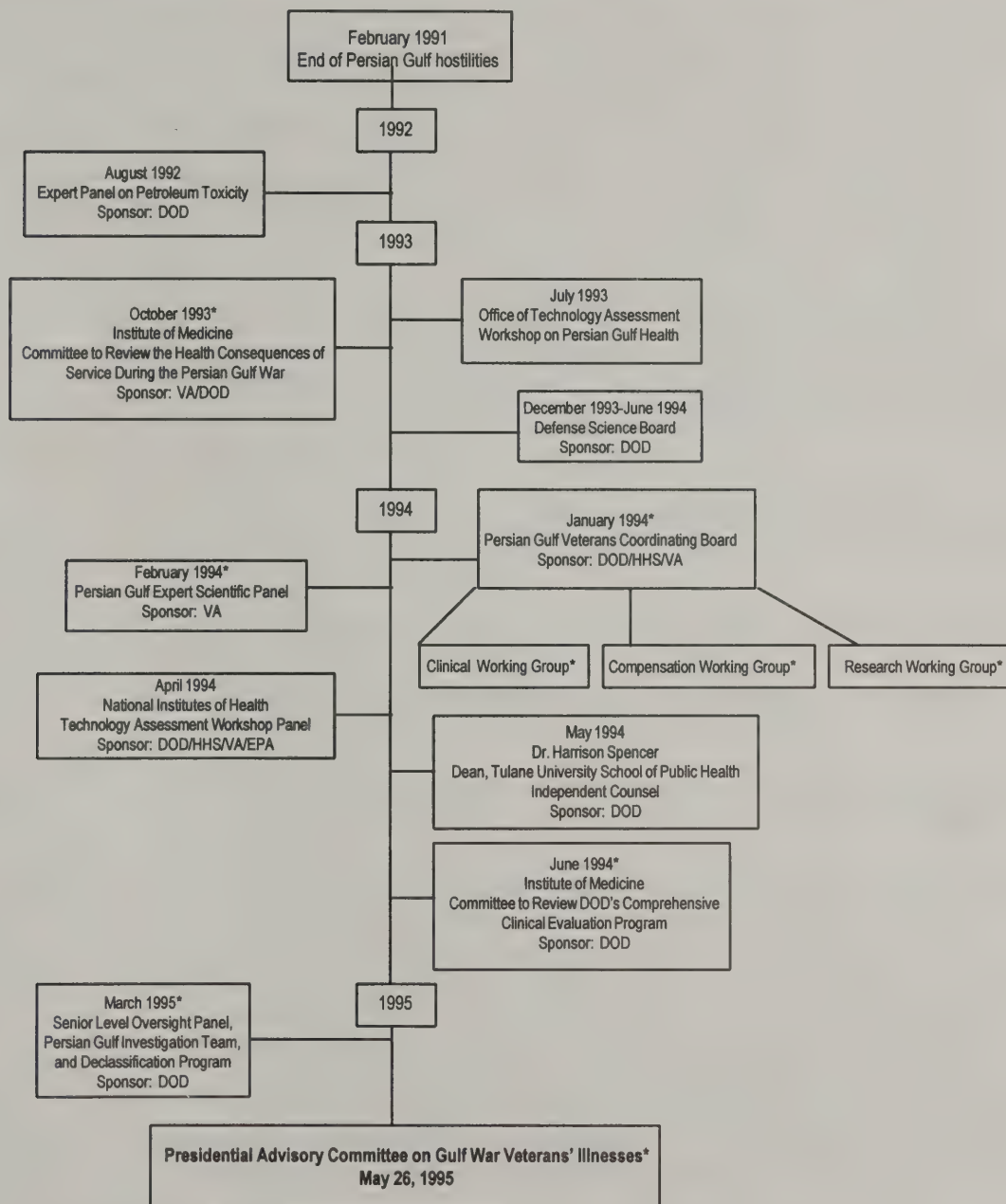
In parallel with obtaining information related to the interim report, the Committee and staff have been gathering data to address issues not addressed in this document. The Committee's work plan for the next 10 months

The Committee has received testimony from the public and government officials and reviewed scores of reports related to Gulf War veterans' illnesses.

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appears in Chapter 6. Many important questions remain for us to address and, hopefully, help to resolve.

Securing a healthy future for Gulf War veterans is of paramount importance to President Clinton. We promise our full dedication to his charge.

Figure 1--Key Committees on Gulf War Veterans' Health Issues

* Current Committee/Group

Chapter 2

Outreach

The U.S. government responded to Gulf War veterans' illnesses with extensive clinical care and research programs. For those programs to be successful, however, veterans, their families, and their communities must know about and use them. DOD and VA have incorporated several communications media in their outreach programs, including telephone, on-line, print, and broadcast services.

The Committee initiated its review of the government's outreach programs—all efforts to educate veterans and the public about Gulf War veterans' illnesses and the health care and disability benefits available to veterans—with four key questions:

- Do the outreach programs use sensible methods to educate the interested public and Gulf War veterans?
- Is there sufficient coordination within each department and between DOD and VA in the implementation of the outreach program components?
- Do the departments use any performance measures and self assessment techniques to determine which outreach program components work best?
- Are lessons learned in the development and implementation of Gulf War veterans outreach programs applicable to future situations?

For this interim report, we evaluated how DOD and VA use several communications tools and the clarity of their message. The IOM also has reviewed outreach to Gulf War veterans.⁶ In 1995, IOM recommended "VA improve publicity regarding the existence of the Persian Gulf Health Registry, and encourage all concerned PGW veterans to be registered." Subsequently, VA expanded its outreach campaign to include a toll-free number, which was established in February 1995. We make additional findings and recommendations about VA's and DOD's outreach in this chapter.

BACKGROUND

For active duty forces—including sailors deployed at sea and soldiers stationed in foreign countries—even common news and information can be difficult to access. For veterans, like all Americans, the communication diffi-

culties lie in cutting through the information filters of a diverse and dispersed populace. The challenge to DOD and VA is to formulate methods of communication that will effectively reach their unique audiences. The Committee has assessed their adherence to basic public health outreach principles, i.e., educating and referring the target population through efficient methods of communication.

DOD and VA also face bureaucratic challenges. With large organizations, effective communication with clients requires careful coordination among bureaus or divisions with disparate responsibilities. Intra- and inter-departmental coordination is critical to clarity of message and to marshalling resources and expertise. The Committee has assessed the effectiveness of existing coordination efforts and considered possibilities for enhancement.

Telephone Services

To date, the federal government has used three toll-free numbers to reach Gulf War veterans, one operated by VA and two by DOD.

DOD Persian Gulf Medical Registry Hotline (Hotline) (1-800-796-9699). The Office of the Assistant Secretary of Defense (Health Affairs) established DOD's toll-free Hotline on June 23, 1994. The Hotline's primary function is referring eligible persons to medical treatment facilities to participate in DOD's Comprehensive Clinical Evaluation Program (CCEP). Operators do not answer clinical questions; they inform callers (approximately 30,000 to date) that questions will be answered during the CCEP evaluation process.

Operators work with a script to register eligible callers and family members. Once registered, callers may receive a referral to a medical treatment facility if desired. The operators use a specially designed database to locate the medical treatment facility nearest a caller, who is notified to expect contact from the facility within two weeks. The computer system transmits caller data to the treatment facility along with verification of eligibility for evaluation.* Callers eligible for medical coverage from VA, but not DOD, are referred to VA's Helpline. Callers receive a letter confirming the registration and/or referral.

Callers can request placement in DOD's database without seeking medical evaluation. These requests can occur when an individual who is not sick nevertheless wants his or her name in the registry in the event of future illness. Some callers are not eligible or have family members who are not eligible for access to DOD medical facilities, but ask to register in the event that access rules change.

The DOD Hotline operators use a specially designed database to locate the medical treatment facility nearest a caller.

*Those eligible for medical evaluation from a DOD facility are: active duty and active National Guard personnel; members of the selected, individual ready, and standby Reserves; regular or reserve retirees eligible to receive military retired pay; reserve retirees not yet eligible to receive military retired pay; nonmilitary members who served in the Gulf as civilian government employees; and eligible family members.

DOD has collected data on the number of callers requesting referral who have not been contacted in the two-week period and have called the hotline for referral. Overall, 17 percent of CCEP participants had to be referred a second time, but in the past few months the rate has declined to less than 10 percent. This improvement reflects some decentralization in the referral process and could indicate personnel in the medical treatment facilities are becoming more familiar with the Hotline referral process.

DOD intramural coordination among Health Affairs, Public Affairs, and the American Forces Information Service (AFIS) played an important role in the promotion of the Medical Registry Hotline. The Hotline was conceived by Health Affairs, publicized to the press and media through Public Affairs, and communicated to the service members through AFIS.

VA Persian Gulf Helpline (Helpline) (1-800-PGW-VETS). VA established its toll-free Helpline on February 2, 1995. VA's Helpline serves as a point of information dissemination, not as a point of entry into the Persian Gulf Health Registry. Operators are supposed to refer callers requesting an examination to a point of contact at the VA medical treatment facility nearest them. As of November 1995, the Helpline had received over 115,000 calls. Call volume data suggest the Helpline number has been effectively communicated to the public.

The initial contact on the Helpline is the automated voice mail service. The auto-attendant offers a range of information about benefits and services, medical benefits, and disability compensation. Recorded instructions prompt callers to access different parts of the voice mail script. Live operators can be accessed at various points, most notably when the caller requests forms or other information not in the recorded script. Direct access to an operator also is available if the caller does not have a touch tone telephone. The auto-attendant records messages after normal business hours, and the operators process the appropriate responses on the next working day. Callers who request information about any particular subject from the auto-attendant receive an information package containing the following items: *Persian Gulf Review* newsletter; question and answer pamphlet on Gulf War veterans' illnesses; ongoing research pamphlets; available medical care program pamphlet; disability compensation form; and Persian Gulf Illness fact sheets.

Intramural coordination between VA's Veterans Health Administration (VHA) and Veterans Benefits Administration (VBA) played an integral part in establishing the Helpline. The Veterans Assistance Service, a component of VBA with expertise in operating phone systems and hotlines, worked with VHA clinicians to create the auto-attendant script for the Helpline and to train the operators, who are contractors. The Helpline operates on a joint VBA-VHA budget. Ongoing consultation between the administrations assures the script is current and accurate.

As of November 1995, the VA Helpline had received over 115,000 calls.

**Veterans of the Gulf War, but not their spouses or dependents, are eligible for the Persian Gulf Health Registry.

DOD Incident Reporting Line (1-800-472-6719). DOD's Incident Reporting Line, a toll-free line, began operating May 30, 1995. Operators record details of incidents in the Kuwaiti Theater of Operations that callers believe could have led to illnesses suffered by any Gulf War veteran. DOD also encourages physicians to call when they believe they have medical information about the causes of health problems suffered by Gulf War veterans. The line is staffed by the same operators who staff the Persian Gulf Medical Registry Hotline, but they use a different database that allows them to categorize an incident as well as write a brief descriptive narrative (1,000 characters or less). Each caller receives a letter confirming the incident report. All recorded information is sent to the Persian Gulf Investigation Team (PGIT) in Washington, DC, which follows these leads for DOD (see Chapter 5). Over 1,000 incidents have been reported to date.

The Incident Reporting Line has been publicized through the same media as the Hotline. DOD also placed the telephone number of the Incident Reporting Line on the leave and earnings statements received by active duty, National Guard, and Reserve members for a three-month period beginning in September 1995.

On-line Services

Increasingly, the government, corporations, and individuals take advantage of the Internet and World Wide Web (Web) as a method of information outreach. DOD and VA utilize on-line services to disseminate information to Gulf War veterans. Several privately-developed Web sites devoted to Gulf War veterans can be found by browsing the Web. Though many service members and veterans do not have access to a computer to retrieve this type of information, Internet resources do serve the public at large and undoubtedly reach some service members and veterans.

DOD GulfLINK (<http://www.dtic.dla.mil/gulflink/>). DOD has a broad-based Web site, DefenseLINK, and in August 1995 opened the Web site GulfLINK, which is devoted to Gulf War issues. GulfLINK provides users access to a variety of topics, including reports on Gulf War veterans' illnesses, recently declassified Gulf War documents, fact sheets, press releases, bibliographies, speeches, and other special features. There is also a home page for the Assistant Secretary of Defense (Health Affairs), which includes a section devoted to Gulf War veterans' illnesses. The Internet site address recently was listed on September through November 1995 military leave and earnings statements.

GulfLINK provides education and information services in a user friendly medium and has been publicized through press releases and news conferences. As of January 1996, there have been more than 98,000 accesses to GulfLINK.

Also as of January 1996, GulfLINK contained more than 10,000 pages of recently declassified intelligence documents. DOD provides no criteria for assessing the reliability of many declassified documents posted on GulfLINK,

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particularly Intelligence Information Reports (IIRs) containing raw human-intelligence information from the field. The GulfLINK home page merely notes that "IIRs are not finally evaluated intelligence. Reports are from all types of sources which have not been assessed for reliability or veracity." In briefings for Committee staff, the Defense Intelligence Agency (DIA) questioned the accuracy of many of its own field intelligence reports posted on GulfLINK, particularly more than a dozen IIRs reporting the deployment of Iraqi chemical munitions to the Gulf War theater. DIA explained the reports in question lacked sufficient corroboration or were otherwise implausible.

VA On-line (1-800-US1-VETS) and VA Web Page (<http://www.va.gov/health/enviro/persgulf.htm>). VA On-line, a computer bulletin board for personal computer users, provides the same information offered by the voice mail of the Helpline in a text format. Users can download information from the bulletin board. The service appears to be utilized heavily, with close to 128,000 accesses and nearly 66,000 downloads of information since its inception in February 1995.

Like DOD, VA also has a Web home page. Usage has increased steadily during the last year, to nearly 30,000 accesses per week. In December 1995, VA added a "Persian Gulf Veterans' Illnesses" page to its main home page. This site offers information on the Persian Gulf Veteran's Health Registry, National Health Survey, research initiatives, and telephone numbers to VA's Helpline and DOD's Hotline.

Print Media

Print media—via targeted efforts or mass mailings—also offer DOD and VA opportunities for outreach to Gulf War veterans.

Leave and Earnings Statements. DOD publicizes programs for service members through biweekly or monthly leave and earnings statements. As mentioned earlier for example, DOD placed the Incident Reporting Line toll-free number on the leave and earnings statements issued in September 1995. A spike in call volume in the third week of September—a 138 percent increase over the previous week—suggests this is an effective outreach tool. The CCEP Management Team is in the process of placing the Hotline number on leave and earnings statements.

Newsletters and Memos. VA policy calls for sending all members of its Health Registry a quarterly newsletter entitled *Persian Gulf Review*. This publication contains information about current research efforts, treatment protocol updates, report releases, and any other items about which VA feels Gulf War veterans should know. VA also highlights its toll-free number on pamphlets at VA medical centers.

In the past, Secretary of Defense Perry and Secretary of Veterans Affairs Brown have sent out signed memoranda detailing changes and updates in

The Defense Intelligence Agency questioned the accuracy of many of its own field intelligence reports posted on GulfLINK.

Secretary of Defense Perry and Secretary of Veterans Affairs Brown have sent out signed memoranda detailing changes and updates in policies concerning Gulf War veterans.

policies concerning Gulf War veterans. Confusion exists, however, about who received the May 1994 memorandum from Secretary Perry (and Chairman Shalikashvili) informing Gulf War veterans of the availability of DOD and VA medical evaluations for Gulf War veterans experiencing health problems. Some Gulf War veterans (including those on Committee staff) have informed the Committee that they never received the memorandum. DOD states it was sent to approximately 110,000 separated veterans who would not receive that information through active duty channels. Slightly more than 18,000 were undeliverable. A second mailing in October 1994 was sent to nearly 24,000 separated veterans and about 7,500 were undeliverable. DOD reports that since active duty personnel "have access to chain of command message traffic and other forms of ongoing communication" the intent was to reach only separated veterans.

Public Service Announcements (PSAs). During 1995, VA distributed a PSA publicizing the Helpline, VA medical and compensation benefits, and symptoms experience by some Gulf War veterans. The cumulative circulation of the newspapers carrying the article was over 3 million, but there is no method of determining how many Gulf War veterans saw this PSA. VA has no means of tracking every newspaper publication of the PSA, thus no correlation can be made to Helpline usage or entry into its Health Registry.

On August 27, 1995, *Parade* magazine prepared and published a PSA explaining the predominant symptoms experienced by Gulf War veterans and printing DOD's Hotline and Incident Reporting Line and VA's Helpline telephone numbers. The call volume data from the following week show no significant increase in calls to either number.

Broadcast Media

Both DOD and VA have used radio and television in their outreach to Gulf War veterans.

DOD—AFIS/AFRTS. AFIS, DOD's internal information service, offers news, sports, and entertainment programming to service members worldwide. The Armed Forces Radio and Television Service (AFRTS), the broadcast service of AFIS, delivers radio and television programs—including many of the same programs seen on commercial television in the United States—to one million service members overseas and aboard ships at sea. AFRTS distributes programming to these sites by satellite and mail-delivered video and audio tape. Through its Print Media Directorate, AFIS oversees the European and Pacific editions of the *Stars and Stripes* newspapers and exercises editorial control over the 1,100 military funded DOD newspapers in the U.S. and around the world. DOD has consolidated all public affairs, broadcasting, photo sciences, equipment maintenance, and audiovisual training under AFIS. AFIS appears to have substantial leverage in providing outreach to service members worldwide.

VA Public Service Announcements (PSAs). VA broadcasts PSAs over public and private stations to publicize the Helpline, which is the department's

primary outreach effort to Gulf War veterans. VA's target audience is quite broad, and PSAs can reach millions of people. Data on how many Gulf War veterans actually see or hear them are unavailable. Viewership estimates exist, but radio and TV stations do not always report when and if they have aired or published the spots.

The Committee reviewed several VA PSAs. None mentions illness or any specific reason to call the Helpline. The PSAs fail to use any of the terms most familiar to the public or to veterans to convey their message.

Clarity of Message

Communication through outreach programs plays an essential role in health promotion. It is challenging to convey health information about illnesses for which causes are uncertain, controversial, and subject to change with new findings. Certainly some of the health problems affecting some Gulf War veterans fall into this category. With so many clinical and administrative issues involved in treating these veterans, outreach to them and their families must be clear and accurate.

As the Committee received public comment from Gulf War veterans and other interested parties over the past months, we heard several times that the term "priority care" associated with the VA health care system is misleading to some Gulf War veterans. Many believe they have "head of the line" privileges over others when receiving medical care. VA, which uses the term because it was included in statutory language, states "priority care" in this context actually means VA is required to treat the veteran's illness, despite a lack of any indication that it was the result of Gulf War service, unless the examining physician determines that it is from a cause that is not related to service in the Gulf.

With so many clinical and administrative issues involved in treating these veterans, outreach to them and their families must be clear and accurate.

FINDINGS

- DOD's Persian Gulf Medical Registry Hotline and VA's Persian Gulf Helpline effectively educate callers about the availability of the CCEP and the Persian Gulf Health Registry, respectively. Both telephone systems adequately refer callers to points of contact at medical treatment facilities.
- DOD's GulfLINK offers a user friendly, accessible resource that deposits information pertinent to Gulf War veterans' illness in a central location.
- Since GulfLINK contains contradictory intelligence reports, the net effect of posting these declassified documents on GulfLINK could be to confuse rather than enlighten the interested public. Without a better system for organizing and presenting information, persons using the resource could gain false impressions or misunderstand documents.

- Although mailings such as the memorandum from Secretary Perry and Chairman Shalikashvili can be expensive, they are a reasonable method of getting information to the concerned population.
- VA's On-line service and World Wide Web home page provide computer users with a widely accessible Gulf War veterans' illness education and referral resource.
- VA's print PSA gives readers useful information on Gulf War veterans' illnesses. VA's broadcast PSAs, which publicize the Helpline number but do not mention illness or potential illness as a reason to call, need improvement.
- VA's use of the term "priority care" in reference Gulf War veterans' eligibility for health care creates false expectations among a significant portion of its clientele.
- Public and congressional concern for the health of Gulf War veterans has been evident since the world witnessed the 1991 oil well fires on television. DOD did not set up hotlines or sites at medical treatment facilities to provide information and medical referral services to Gulf War veterans until 1994, a significant delay in response time.
- VA's Helpline started late in comparison with its other efforts to address the issue of Gulf War veterans' illnesses. It was established two years after the initiation of the Persian Gulf Health Registry and one year following the passing of Public Law 103-210, which initiated "priority care" services. VA had conducted some outreach in tandem with the establishment of the Health Registry, but its *Persian Gulf Review* newsletter was sent only to those already participating in the Health Registry.

RECOMMENDATIONS

- Operators at the DOD Medical Registry Hotline, DOD Incident Reporting Line, and VA Helpline should be instructed to ask "How did you find out about this number?" as a method of qualitatively measuring the success of the different methods for publicizing the numbers.
- In the next CCEP end-of-evaluation questionnaire, which participants answer when the initial evaluation is completed, DOD should include a question about satisfaction with the referral provided by the Persian Gulf Medical Registry Hotline.
- DOD and VA should utilize more refined performance measures to determine how well the services are reaching concerned parties. Caller volume data are not adequate.
- To assist the general public in interpreting the declassified intelligence documents on GulfLINK, DOD should prepare a user's guide. This

guide should explain in general terms the various sources of intelligence information, how they may differ in quality and reliability, and how intelligence analysts compile and evaluate reports from a variety of sources in the field to obtain corroboration before preparing a final assessment. This guide should be featured prominently on the GulfLINK home page.

- VA should make its broadcast PSAs regarding the Helpline more explicit. The PSAs should include brief explanations of the purpose of the Helpline and the referral process for the Persian Gulf Health Registry.
- Future conflicts are likely to generate controversial and unexplained health concerns, and DOD and VA should anticipate the need and plan for outreach services and implement them expeditiously.
- In its outreach campaign, VA should forego use of the term "priority care." It should state clearly that Gulf War veterans are entitled to receive the Persian Gulf Health Registry examination free of charge, including any diagnostic testing found to be medically necessary and counseling regarding findings.

Chapter 3

Medical and Clinical Issues

The United States prides itself on maintaining a strong, volunteer fighting force and on providing excellent benefits for its veterans. Increasingly, the military depends on a healthy, well-trained, and deployable reserve force. Of the 697,000 participants in Operations Desert Shield/Desert Storm, 17 percent came from the Ready Reserves (members of National Guard and Reserve units).

BACKGROUND

For this interim report, the Committee focused on three medical treatment issues that surfaced during the deployment and demobilization of troops: the adequacy of medical screening and evaluation; the use of unapproved drugs and vaccines; and the quality of medical recordkeeping in theater. In 1994, the DSB Task Force concluded that DOD needs substantial improvements in pre- and postdeployment medical assessments and data handling.³ We agree, and make specific findings and recommendations in these areas in this chapter.

The Senate Veterans' Affairs Committee examined the decision to use investigational products (i.e., drugs or vaccines not yet approved for the purpose used) as protective measures against chemical and biological warfare in the Gulf War in a 1994 hearing that explored broad issues related to military research.⁹ The findings and recommendations for future government actions that we discuss in this chapter are more limited in scope.

Predeployment and Postdeployment Medical Assessment

DOD has established medical and fitness standards to ensure all forces can perform their military duties. Identical standards apply to active and reserve personnel.

Establishing Fitness for Deployment. Active duty forces undergo continual medical and fitness surveillance and have access to military health care. The Ready Reserve relies on other mechanisms, including periodic physical examinations and regular self-reports on health status, to ensure readiness for activation. The Assistant Secretary of Defense (Health Affairs) sets DOD medical fitness policy, and the services are responsible for implementation.

The policy identifies the diseases and medical conditions that may render active service members unfit for military duty and also applies to reserve personnel while in an active status. According to testimony before the Committee, personnel were considered medically unfit for deployment due to one of the specified medical conditions, e.g., asthma, diabetes, pregnancy.

At the time of Operations Desert Shield/Desert Storm, DOD-wide policies called for medical examinations at four-year intervals and annual certificates of physical condition for Ready Reserve members of all services. Each military service could require more frequent examinations if considered necessary for mission-specific reasons. These policies, however, were not uniformly enforced across the services, particularly with regard to annual certifications. For example, the Navy and Marine Corps Ready Reserves required their members to submit annual statements indicating any changes in health status since their previous statements. The Army had no formal documented requirement, although some unit commanders required documentation of health status. The Air Force monitored physical condition through monthly unit procedures, but did not require members to submit an annual certification.

Each service implemented its own predeployment screening program for reservists, but three components were common to all:

- a medical records review, including a review of immunizations, HIV status, and validation of medical and dental status;
- self-certification of health status; and
- appropriate referral to health care providers as necessary.

Only Air Force regulations required a physical examination in addition to the record screening and health questionnaires of the other services. This requirement was waived for members whose periodic physical examinations had occurred within the past year.

Despite readiness requirements, DOD found significant numbers of reservists were nondeployable at the time of Operations Desert Shield/Desert Storm. DOD was unable to provide the Committee with comprehensive data about reservists found to be nondeployable, asserting that its emphasis was on expediting deployment rather than maintaining databases on the nondeployed. Some service-specific information, however, is available:

- A 1991 Army Inspector General Report concluded that perhaps as many as 8,000 Army reservists were nondeployable for medical reasons upon arrival at the mobilization sites. After further evaluation and/or treatment, all but 1,100 of these were eventually deployed, but dealing with the nondeployables disrupted the mobilization process. Unit commanders told the Inspector General that medical problems kept approximately another 8,000 personnel from ever leaving their home units.

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- The Inspector General, U.S. Sixth Army, also addressed the problem of medically nondeployable personnel. While not specifying numbers, the report stated that many soldiers deployed to Southwest Asia had to be sent back to the United States because of medical conditions not previously diagnosed.
- The Navy reported that approximately 400 reservists were mobilized but not deployed after medical problems were identified.
- The Air Force documented almost no personnel unable to deploy.
- The Marines could provide no information on reservists found to be nondeployable.

Health Screening of Demobilized Gulf War Veterans. At the time of demobilization, DOD policy required each member of the Ready Reserve released from active duty to receive a separation physical examination established in accordance with individual service directives. The Army extended this requirement to both regular duty and reserve members and published specific guidance detailing the components of the postdeployment physical examination. The Air Force authorized a separation physical examination at an individual's request; if the member's previous physical examination was less than five years old, the scope of the examination consisted of a detailed medical history with a physical examination focused only on problem(s) identified. The medical records of Navy and Marine Corps reservists being returned to a drill status were reviewed, and reservists were asked about changes in health status; members without changes to report signed statements to that effect and were released. The Committee has received testimony that these demobilization medical screenings did not uniformly occur in the rush to return reservists to their civilian lives.

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Policy Changes Post-Gulf War. The General Accounting Office (GAO) identified a number of problems in DOD's policies and procedures and made recommendations to correct them.⁷ DOD concurred with most of GAO's findings and agreed to take the necessary actions to correct the problems.

The Assistant Secretary of Defense (Health Affairs) has mandated the use of a standard Report of Medical Assessment Form for all service members separating or retiring. The memorandum, dated May 10, 1995, also directs that any separating or retiring service member who desires a complete physical examination is entitled to receive such an examination.

A draft DOD Instruction, called *Joint Preventive Medicine Support of Military Operations* (now in review), states it is DOD policy:

... that the military departments shall conduct joint preventive medicine support of military operations to include comprehensive medical surveillance. Surveillance shall be in effect continuously for each individual service member throughout their entire period of military service in a manner consistent across the military ser-

vices. The surveillance process shall be specifically configured to assess the effects of deployment on the health of the service member.

Finally, DOD has informed the Committee that it is completing a revision of its accession and retention physical standards. New policies and separation review procedures for members who do not meet physical standards are under review. Moreover, the frequency of routine physical examinations is now five (rather than four) years, with increased emphasis on the annual certificate of physical fitness.

Use Of Investigational Products

During Operations Desert Shield/Desert Storm, DOD anticipated the threat of exposure of U.S. military personnel to chemical and biological warfare. DOD used two investigational products in the Gulf War as prophylactic measures against chemical and biological warfare agents: pyridostigmine bromide (PB), a drug that is classified as an anticholinesterase that binds reversibly with acetylcholinesterase, and botulinum toxoid (BT) vaccine. Anthrax vaccine, an approved (licensed) product, also was used as a prophylactic measure during the Gulf War.

Since PB and the BT vaccine were investigational product as used in the Gulf War, DOD could not have administered them under normal circumstances without the informed consent of the military personnel who received them. The Food and Drug Administration (FDA), however, issued a new regulation in December 1990 that permitted use of these products without informed consent under specific military circumstances. Controversy exists about whether creation of a waiver of informed consent mechanism for these circumstances and use of these particular products with the waiver was appropriate from an ethical, regulatory, and military perspective.

Issuance of the New Rule. An October 30, 1990, letter from the DOD Assistant Secretary of Defense (Health Affairs) to the Department of Health and Human Services (DHHS) Assistant Secretary for Health, requested an amendment to FDA's informed consent regulations to include a combat exigency as a circumstance in which medical professionals could deem it "not feasible" to obtain the informed consent of a person receiving an investigational drug or vaccine. In response FDA formed a task force of government employees that concluded it would be possible to develop a rule that would meet DOD's needs and be protective of the health and welfare of military personnel. FDA published an interim final rule on December 21, 1990, that took effect immediately because of the urgency presented in the military situation;¹⁰ the rule was upheld by the courts.

Under the interim rule, DOD initiates the process of obtaining the waiver of informed consent for a combat exigency by filing a written request with FDA along with an investigational new drug application (IND), a treatment protocol, and evidence that an institutional review board (IRB) has reviewed and

DOD used two investigational products in the Gulf War as prophylactic measures against chemical and biological warfare agents: pyridostigmine bromide (PB) and botulinum toxoid (BT) vaccine.

approved the use of the investigational drug or vaccine without informed consent in the specific circumstances. Subsequently, the Commissioner of Food and Drugs may find that informed consent is not feasible (and thus may be waived) only when withholding treatment would be contrary to the best interests of military personnel and there is no available satisfactory alternative therapy. The rule stipulates four additional, nonexclusive criteria the Commissioner must consider: 1) the strength of the evidence of the safety and efficacy of the drug (or vaccine) for the intended use; 2) the context in which the drug will be administered (e.g., battlefield or hospital); 3) the nature of the disease or condition for which the preventive or therapeutic treatment is intended; and 4) the information to be provided to the recipients of the drug concerning its potential risks and benefits.

Implementation of the New Rule. One week after the interim final rule was issued, DOD requested waivers of informed consent for PB (30 mg tablets) and BT vaccine. The request followed months of deliberations—encompassing political, diplomatic, resource, logistical, and ethical considerations—within DOD. Ultimately, the decisionmaking involved the Secretary of Defense, the Joint Chiefs of Staff, and Central Command (CentCom) in what has been characterized as an intense timeframe extending from August through December 1990. After extensive consultation and scientific analysis, the Commissioner of Food and Drugs approved DOD's waiver requests for BT vaccine and PB on December 31, 1990, and January 8, 1991, respectively.

Decisions about who would actually receive BT vaccine or take PB were made by CentCom based on perceived threat and unit locations. Although FDA issued a waiver of informed consent for PB and BT vaccine, CentCom determined that service personnel designated to receive the BT vaccine should be given a choice as to whether they received the vaccine. CentCom's decision was based on concerns about the ethics of giving investigational vaccines to service personnel and on the insufficiency of vaccine supplies. The perception about PB appeared to differ—i.e., even though this drug was investigational for use in theater, it had been widely used as an approved drug in other populations and, therefore, absence of informed consent was not a cause for concern.

DOD estimates 150,000 service members received at least one dose of anthrax vaccine (an approved biologic) between January 23 and February 28, 1991. About 8,000 troops received BT vaccine in the same period. Approximately 250,000 military personnel took at least one dose of PB, according to DOD estimates.

DOD currently is pursuing approval of BT vaccine and PB. DOD also has asked FDA to make the interim regulation permanent.

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The secrecy of the vaccination program complicated recordkeeping and created some confusion and fear among service members.

Medical Recordkeeping in Theater

During the deployment period for the Gulf War, both active and reserve personnel who developed medical problems were evaluated, treated and returned to duty, hospitalized and returned to duty, or evacuated from the theater of operations. Interactions between deployed forces and medical care providers were recorded in a paper-based system, and much of this information was not incorporated in service members' permanent health records. This breakdown was particularly common for the recording of immunizations given in the theater of operations.

DOD guidelines required field units to maintain rosters of personnel receiving vaccines that included name, Social Security number, rank, and unit. In addition, vaccinations could be recorded on PHS-731 (Yellow shot record) or on SF-601 (Immunization Record).

The secrecy of the vaccination program complicated recordkeeping and created some confusion and fear among service members. Medical personnel in the field received instructions that receiving the shots was classified "Secret" and that the shots were not to be discussed with anyone. DOD asserts the secrecy protected troops since it limited Iraq's knowledge of U.S. defensive capabilities.

When the vaccinations were recorded in medical records retained by individual service members, they were encoded to eliminate document classification problems. Some medical officers have suggested, however, that field personnel were unprepared to deal with what appeared to be classified entries in centrally-maintained medical records, presenting a serious obstacle to proper records management.

According to testimony presented to the Committee, in the flurry of personnel anxious to come home at the end of the Gulf War, much of the documentation about vaccinations was lost or destroyed. DOD maintains rosters of a fraction of the service members who received anthrax and BT vaccines; most are missing. DOD also has reported to the Committee that it is not possible to determine with certainty who actually ingested PB, or in what doses, because service members were supplied PB for self-administration.

FINDINGS

- No uniformity existed among the services in their predeployment or demobilization policies and procedures at the time of Operation Desert Shield/Desert Storm.
- There is little evidence that quality control procedures were employed to ensure that existing policies were actually carried out during deployment or demobilization.

- DOD's policies and procedures were not adequate in all cases to prevent members with preexisting conditions from deploying or to identify health problems extant at the time of demobilization, and these conditions could have contributed to some current health concerns.
- FDA and DOD undertook an urgent and orderly course of action under the circumstances to devise a means to address the real threat of chemical and biological warfare in the Gulf War.
- FDA has not been proactive in addressing public comments on the interim final rule or in devising better long-term methods for governing military use of drugs, vaccines, devices, and antibiotics intended for chemical and biological warfare defense.
- When a waiver of informed consent is granted, the government has a strong obligation to conduct long-term followup of military personnel who receive investigational products.
- DOD did not keep adequate records on who received anthrax and BT vaccines and PB in the Gulf War theater. There is little possibility now of developing reliable data about which or how many persons received those products.
- DOD and VA admit to problems with missing or lost medical records, but neither system appears to place a priority on correcting these problems.
- DOD's rationale for the requirement that records of vaccinations be kept secret was not well understood. This requirement confused and complicated recordkeeping procedures and hindered systematic followup of health issues.
- The issue of accurate medical and vaccination records is central to the concerns of many ill veterans, and the absence of records has been suggested by some as evidence that the government is engaging in a cover-up of its own predeployment practices.

RECOMMENDATIONS

- DOD should regularly review and update the policies and procedures to govern the pre-, during, and postdeployment medical assessment of the Ready Reserve to ensure they are current and adequate.
- DOD should establish a quality assurance program to ensure compliance with pre-, during, and postdeployment medical assessment policies.

- Prior to any deployment, DOD should undertake a thorough health assessment of a large sample of troops to enable better post-deployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services and include timely postdeployment followup.
- Given that FDA's interim rule is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare.
- If FDA decides to reissue the interim final rule as final, it should first issue a Notice of Proposed Rule Making. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long term followup of individuals who receive investigational products; review by an IRB outside of DOD; and additional procedures to enhance understanding, oversight, and accountability. The Committee, at this time, withholds judgment on the adequacy of the current rule.
- DOD should assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data (including classified information, if and when it is needed) in the field. DOD and VA should adopt standardized recordkeeping to ensure continuity.

Chapter 4

Research

The U.S. government has initiated a research program to complement the medical treatment provided to Gulf War veterans. By searching for possible causes of Gulf War veterans' illnesses, the government hopes to improve diagnosis, treatment, and followup and to prevent similar problems in the future.

The government's research program includes epidemiologic studies and toxicologic evaluations of Gulf War risk factors. Epidemiology measures the occurrence of disease in human populations and the factors that influence their occurrence, severity, and outcome. Epidemiologic studies are particularly useful at the early stages of an investigation when the exact nature of a public health problem is unclear or poorly understood. They are also essential to determining whether an array of symptoms occurs more frequently in a particular population.

The Legionnaires' Disease outbreak in 1976 is a good example of epidemiology's role in investigating disease. The Centers for Disease Control and Prevention (CDC) investigated patterns of disease outbreak and transmission to determine that the cause was the previously unknown bacterium, *Legionella pneumophila*, which is found in a variety of water sources. This work laid the foundation for effective treatment of the disease using appropriate antibiotics. In this example, CDC was able to establish a clear link between a specific disease and a specific microorganism.

In comparison, epidemiologic investigations of chronic diseases that might be due to multiple factors often can be less clear cut. Nevertheless, epidemiologic studies will be crucial for helping us understand the impacts of service in the Gulf War on the health of veterans today.

Toxicologic studies of the risk factors encountered during service in the Gulf War are also essential elements of the government's research program. Suspected risk factors include:

- vaccines against biological weapons,
- pyridostigmine bromide,
- various occupational exposures, such as petroleum products and paints,

- psychological and physical stress,
- insecticides and repellents,
- depleted uranium,
- sand,
- smoke from Kuwait oil well fires,
- chemical and biological warfare agents, and
- endemic infectious diseases.

Toxicologic studies use animal and other models to assess indirectly the possible health effects of Gulf War risk factors. Toxicologic studies might be the only means available to evaluate some hypotheses about the effects of certain risk factors on Gulf War participants.

This Committee is not the first external review body to assess federally funded research on Gulf War veterans' illnesses, nor is it the only current effort. The IOM's Medical Follow-Up Agency⁶ has an ongoing evaluation of the research program, as does the VA Persian Gulf Expert Scientific Committee. We are making every effort to coordinate our activities with these other groups while maintaining the necessary independence.

Many other groups, including the DSB Task Force³ and the NIH Workshop Panel⁴, have made findings and recommendations concerning the importance of various risk factors (e.g., oil fire smoke, or infectious diseases) in the government's research scheme. We will take into consideration these findings and recommendations as we proceed with our own analysis over the next 10 months, but our Committee will independently assess health risk factors in the context of our review of the government's research efforts on Gulf War veterans' illnesses.

Toxicologic studies might be the only means available to evaluate the effects of certain risk factors on Gulf War participants.

BACKGROUND

For this interim report, we have focused on two areas: the major epidemiological studies and the Persian Gulf Registry of Unit Locations.

Major Epidemiologic Studies on Gulf War Veterans' Illnesses

The Committee initially has focused on epidemiologic studies being planned or carried out in fairly large populations of Gulf War veterans (Table 1). Our analysis encompassed the following questions:

- Are the study designs adequate to determine whether health problems occur more frequently in Gulf War veterans than in appropriate comparison populations, and to determine what risk factors may be associated with such health problems?
- Are studies directed at the right questions, or are there other questions that should be studied as well?

- Has external scientific review been incorporated to maximize the interpretability and validity of study findings?
- Are the epidemiologic studies being coordinated to assure that research gaps are addressed and redundancy is limited?

Study Design. Epidemiologic studies to examine the health status of Gulf War veterans face several different methodological challenges. Some challenges are common to any epidemiologic study, but others are specific to the circumstances of the Gulf War.

Lack of a case definition. Typically, epidemiologic studies measure the occurrence of a specific disease in populations. Researchers often have a good sense of how that disease manifests itself, how established epidemiologic methods can be applied to measure the frequency and/or severity of the disease in a group of people, and how to search for and interpret linkages with potential risk factors. With the Gulf War veteran population, however, this assessment is more difficult because no specific disease has been defined as the source of reported health problems. Commonly reported symptoms include fatigue, joint or muscle pain, headache, rashes, memory loss, abdominal pain, diarrhea, sleep disturbances, or difficulty in concentrating. The array of illnesses reported by Gulf War veterans has become popularly known as "Gulf War Syndrome."

With the Gulf War veteran population, epidemiologic assessment is difficult because no specific disease has been defined as the source of reported health problems.

External review groups that have examined the existence of a syndrome specifically related to the Gulf War experience conclude that a single, coherent syndrome cannot be defined, even though many illnesses reported by veterans might be attributable to Gulf War service. For example, the April 1994 NIH Workshop Panel found that no single disease or syndrome is apparent, but rather found evidence for multiple illnesses with overlapping symptoms and causes.⁴ The NIH panel concluded it was impossible to establish a single case definition at that time, and that instead, "an evolving case definition might be more appropriately used in developing a research strategy." At this stage, the Committee concurs: no case definition derived in a single population should be applied widely in all studies.

To better understand the illnesses described to date requires more information about the symptoms and their occurrence in the Gulf War veteran population. To this end, the NIH panel made the broad recommendation that DOD and VA establish a more accurate estimate of symptom prevalence. VA has responded to this recommendation in part by launching the "National Health Survey of Persian Gulf Veterans and Their Family Members." This survey is intended to help measure the occurrence of medical problems reported by veterans, and thereby assist both scientific and clinical efforts. Preliminary results of the study should be available in Fall 1996 and final data available in 1998.

Likely low response rates. In an ideal epidemiologic study of Gulf War veterans' illnesses, each participating veteran or active duty service mem-

ber would have a thorough physical examination, face-to-face interview, and medical record review to determine health status and exposure history. Carrying out such complete examinations in a large population, however, is costly and time consuming. Thus, many planned or ongoing studies use postal or telephone surveys to gather data.

Postal surveys, while significantly less expensive than face-to-face interviews, frequently have low response rates. Standard epidemiologic principles caution that if completed surveys are received from less than about 70 percent of the surveyed population, it is difficult to draw conclusions from the study because the responses of a substantial proportion of the sample remain unknown. Nonrespondents can differ from respondents in many important ways, and absence of information from 30 percent or more of a population can introduce biases in the results. For example, veterans with health problems might respond at a higher rate than veterans without problems. To address this issue, studies include efforts to measure the characteristics of a sample of those people who did not respond to determine how they differ from survey respondents. These efforts are necessary, but might not be sufficient to determine the extent and effect of bias from low response rates. Since several of the large epidemiologic studies—including VA's National Health Survey—rely on extensive postal surveys, low response rates could jeopardize some of the major epidemiologic research underway on Gulf War veterans' illnesses.

Selection of appropriate study and comparison populations. Early studies to explore illnesses in Gulf War veterans focused specifically on volunteer respondents from specific units or groups in which Gulf War-attributed symptoms first were reported. Though these studies were useful in characterizing the illnesses in these groups and ruling out some hypotheses, their results cannot be generalized to the Gulf War veteran population as a whole. To obtain data about an entire group, data must be collected from everyone in that group or from a randomly selected sample of the whole population. Collecting comprehensive health data from the approximately 697,000 troops who participated in Operations Desert Shield/Desert Storm is impossible. Hence, to obtain an accurate assessment of the health status of Gulf War veterans, researchers must collect information from a representative sample of that entire group.

Current epidemiologic studies are designed to gather information from more broadly representative samples of the entire Gulf War veterans population. For example, VA's National Health Survey targets 15,000 military personnel who participated in Operations Desert Shield/Desert Storm. The sampling is being carried out so that the military branch and unit status of those surveyed represents the Gulf War veteran population, with extra sampling of women and reserve/guard veterans so that the sample of these relatively smaller groups will be large enough to draw useful conclusions. A second VA study of Gulf War veterans intends to capture information on mortality in virtually all Gulf War veterans and a comparison veteran population to provide as complete information as possible on comparative rates and causes of deaths.

Since several of the large epidemiologic studies—including VA's National Health Survey—rely on extensive postal surveys, low response rates could jeopardize some of the major epidemiologic research underway on Gulf War veterans' illnesses.

The ability to draw conclusions about whether Gulf War veterans are experiencing more or different health problems than expected clearly depends on the ability to identify a suitable comparison population. Worker populations are characteristically healthier than the general population, because people with serious health problems are less likely to be in the work force; workers thus would typically be compared to another similar worker population. Moreover, active duty military personnel are likely to be healthier than typical U.S. workers because of the physical demands of the military. Hence, it would be inappropriate to compare the health of Gulf War veterans to the general civilian or specific civilian working populations. The ideal comparison population would be identical to the Gulf War veteran population in every way except for deployment to the Gulf region.

To address this important issue, the Defense Manpower Data Center (DMDC) constructed a roster of all people assigned to military units that served in the Gulf area and also compiled a list of about 1.5 million troops who served in the military at the same period as the Gulf War but who did not serve in the Gulf War theater. This group of 'era veterans' still might not be the ideal control group if it differs from troops deployed to Southwest Asia in ways for which researchers cannot adjust—e.g., service members deployed to the Gulf War could have been the most physically fit. Nonetheless, era veterans are considered the best group for comparison to Gulf War veterans, and this roster will be used as the comparison population in VA's National Health Survey and other studies.

Self-reporting health outcomes and exposure. As noted by DOD's Armed Forces Epidemiology Board, self-reporting of health outcomes and exposures is a major and significant limitation of all current epidemiologic studies of Gulf War veterans. In most ongoing studies researchers ask veterans to recollect or self-report any health problems—depending on the case, this recollection can amount to a self-diagnosis of one's own conditions. To some extent, self-reported health problems can be validated by cross-checking with other sources of information, such as hospital records, state disease and birth defects registries, or clinical examinations of veterans. The government's current epidemiologic studies stand to gain tremendously by their planned physical examinations and medical record searches to validate self reports on health problems for a subset of study participants.

In contrast, self-reported exposure estimates are much more difficult to validate by other external sources. Epidemiologists recognize that relying on self reporting to determine exposure information carries problems of possible biases in recollection.

Expectations of current studies. Current major epidemiologic studies will compare health problems experienced by large subsets of Gulf War veterans. These studies are not likely to detect a small veteran subpopulation that has health problems because of unique exposure situations. Such questions

Self-reporting of health outcomes and exposures is a major and significant limitation of all current epidemiologic studies of Gulf War veterans.

The Iowa researchers report that the public advisory committee has played an important role in simplifying the wording of their study questionnaire, in stressing the need to safeguard the confidentiality of questionnaire responses, and in disseminating information about the study to veterans groups.

cannot be effectively addressed until testable hypotheses are developed about the specific smaller groups that might be expected to have those greater risks. The Persian Gulf Registry of Unit Locations database could help identify potentially higher-exposure subgroups. Other ongoing studies might clarify the absence or presence of susceptibility factors relevant to particular exposures.

External Review. The methodological issues just mentioned are only a few of the many important limitations and challenges faced in the design and execution of epidemiologic studies of Gulf War veterans. Other critical issues include the adequacy of population sample size, effectiveness of survey/questionnaire design, and limitations in the use of medical records or registries for gathering or validating health information. Because of resource constraints, difficult choices frequently must be made in designing such studies. For example, more questions on a survey questionnaire allow for more specific information to be gathered, but the increased length often results in fewer people completing the questionnaire.

External scientific review is invaluable as these issues are faced and tradeoff decisions are made. No matter how large and qualified an individual study team, any study benefits from external and independent perspective and input throughout research design, data collection, and analysis. External scientific review of the current major epidemiologic studies has ranged from nonexistent, to one-time review of protocols, to standing scientific advisory panels with an ongoing role in the design and execution of the studies. The responsiveness of principal investigators to external review varied as well.

A public advisory committee also has proved useful to at least one study now underway. Iowa researchers funded by CDC have a science advisory committee and a 20-member public advisory committee composed of Gulf War veterans, spouses of veterans, and representatives of veterans service organizations. The Iowa researchers report that the public advisory committee has played an important role in simplifying the wording of the study questionnaire, in stressing the need to safeguard the confidentiality of questionnaire responses, and in disseminating information about the study to veterans groups.

Study Coordination and Oversight. External scientific review of individual studies can greatly improve quality, but it cannot ensure that the overall research agenda encompassing all of the individual studies is adequately served. In fact some studies deemed not useful and potentially misleading by external reviewers have been continued. Coordinating the government's epidemiologic studies and other studies being funded within the larger context of research into Gulf War veterans' illnesses can ensure priorities are set, appropriate research questions are addressed, and unnecessary duplication is avoided. Since resources are limited, judgments must be made about which research endeavors can provide the most useful information.

The Persian Gulf Veterans Coordinating Board, comprising the Secretaries of Defense, Health and Human Services, and Veterans Affairs, was established in January 1994. It is charged with providing direction and coordination on health issues related to the Gulf War. The Coordinating Board's Research Working Group, which has primary responsibility for Gulf War-related research, describes its responsibilities as:

- coordinating studies to avoid unnecessary duplication,
- ensuring a focus on high priority research relative to Gulf War veterans' health issues,
- assessing the status and direction of federally funded research,
- identifying possible gaps in our understanding of Gulf War veterans' health issues,
- recommending future research directions,
- serving as a forum for research data exchange among the three departments, and
- generating periodic reports to federal oversight authorities.

The major contribution of the Research Working Group has been the publication of *A Working Plan for Research on Persian Gulf Veterans' Illnesses* in August 1995 and a series of meetings at which principal investigators have discussed details of their research. In testimony before the Committee, there has been no clear indication that this group has had a significant impact on the existing major epidemiologic studies, even in cases where external reviews have suggested that certain studies would not make a positive contribution to the overall research effort.

Several previous external reports that reviewed various portions of federally funded research on Gulf War veterans' illnesses recommended overall, centralized coordination. In 1995, the IOM Committee on Health Consequences of Service During the Persian Gulf War⁶ wrote that studies completed before 1994 on Gulf War veterans' health issues had been piecemeal, and recommended that VA and DOD determine the specific research questions that need to be answered and design epidemiologic studies accordingly. IOM specifically recommended that VA and DOD "collaborate to obtain population-based and controlled data on symptom prevalence, health status, and diagnosed disease." Our own findings and recommendations concerning the major epidemiologic studies reinforce this view.

A good example of the need for coordination and oversight is the debate about standardizing study questionnaires. Most experts agree that it is not desirable to make all questionnaires from all studies identical. Nevertheless, when specific questions from different studies are aimed at obtaining the same information, then consistency offers the advantage of allowing future inter-study comparisons. The Office of Management and Budget (OMB) initiated this type of coordination for epi-

The Persian Gulf Veterans Coordinating Board is charged with providing direction and coordination on health issues related to the Gulf War.

demologic studies of Gulf War veterans. Under the authority of the Paperwork Reduction Act, OMB has required that the principal investigators of several studies revise their individual questionnaires to reflect a common, core set of questions on symptoms and conditions.

OMB's role in enforcing some questionnaire standardization is controversial. Some researchers believe it is too early in the understanding of the Gulf War veterans' illnesses to stifle independent experimentation and innovation in the research process by dictating some portion of the questionnaires. The Research Working Group has not played an active role in the debate.

The Persian Gulf Registry of Unit Locations

The Gulf War theater posed significant barriers for collecting exposure data on the various risk factors that might effect the health of service members months or years later. Plainly put, the military's goal is to successfully carry out the mission of the war, not to collect research data. Nevertheless, the lack of good exposure data for Gulf War veterans has certain consequences today for evaluating the long-term health impacts of service in Southwest Asia.

For example, DOD has precise information about the pesticides shipped to the Gulf, but information about who used them and when is fragmented at best. Such information might have allowed an estimation of individual exposures. The only available information to estimate individual exposures for most Gulf War risk factors is recollections by veterans, and these will be difficult or impossible to validate.

There is no way to compensate fully for the lack of good exposure data related to Gulf War service. As a consequence, it will be difficult to link health problems discovered in epidemiologic studies with specific exposures. In this, the country has not avoided repeating the mistakes of the past. For example, the 1994 IOM report *Veterans and Agent Orange* found the numerous health studies on Vietnam veterans were hampered by the lack of good individual data about exposure to dioxin or herbicides, though even without such data epidemiologic studies were useful for evaluating veterans' health status. Nevertheless, to evaluate the potential impact of a specific Gulf War related risk factor, quantitative information about the size and timing of the exposure is crucial, and few data are generally available for many risk factors. New draft guidance under development by DOD indicates the issue of better exposure records and medical surveillance of troops has become a higher priority for future conflicts. The Committee will evaluate these efforts in the coming months.

Some investigators anticipate DOD's Persian Gulf Registry of Unit Locations database will provide exposure information that will be unavailable from any other source. In December 1991, Congress required that DOD produce a database on those who served in the Gulf War (Public Law 102-190). Although Congress mandated the database in response to con-

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cerns about smoke from Kuwait oil fires, the database is likely to be relevant to other possible exposure assessments.

The Environmental Support Group (ESG) of DOD intends for the database to provide personnel and unit data for research purposes; the database also establishes the location of units, which may be useful in evaluating future health claims. ESG hopes to produce a database with at least one location coordinate for each unit (company level) from January 15, 1991, to the time that unit left the Gulf region. Both the IOM Committee⁶ and this Committee have commented that the Persian Gulf Registry of Unit Locations database needs to be completed as quickly and accurately as possible. However, DOD projects the database will be available to researchers by April 1996 at the earliest—over a year after IOM's initial call and the original goal set by DOD.

Though location data will be at the resolution of an individual unit and will not be specific to an individual, it could prove an important resource for exposure information on Gulf War troops. For example, a time series of geographic location of troop units might be useful to distinguish between units that were in the vicinity of Kuwait oil fires from troops that were not in the vicinity. Such data would be useful in epidemiologic studies evaluating the possible health effects of exposure to Kuwait oil fire smoke.

Some investigators hope to use the Registry of Unit Locations database to assess other exposures. For example, it might be possible to determine which troop units were in the vicinity of depleted uranium (DU) weapons (e.g., tank battles). Such a population might be expected to have a greater potential exposure to DU than other troop units. Investigating possible disease clusters is another potential for this database. Some investigators are intrigued with the possibility of looking for clusters of certain diseases or symptoms among specific units—e.g., clusters in units closest to damaged Iraqi chemical weapon depots.

The Registry of Unit Locations is unlikely to be informative for most missing exposure data. It will reveal little about exposure to pesticides, pyridostigmine bromide, vaccines, or other health risk factors because little information exists about how, when, or by whom such agents were used during the Gulf War. The limited resolution at the unit level means exposure information for a specific service person might be prone to error; individuals did not always physically remain with their units.

DOD's Registry of Unit Locations will reveal little about exposure to pesticides, pyridostigmine bromide, vaccines, or other health risk factors because little information exists about how, when, or by whom such agents were used during the Gulf War.

FINDINGS

- Despite the unique features of the Gulf War, it should be possible using epidemiologic approaches to determine whether Gulf War veterans have more or less mortality, symptoms, or diseases than an appropriately chosen comparison population.

- Most of the studies examined by the Committee appear to be well-designed and appropriate to answer questions about mortality, symptoms, or diseases.
- Some studies currently underway or planned at best will add little information to other better designed studies and could provide misleading information, leading to false conclusions.
- External scientific review of the major epidemiologic studies has ranged from nonexistent, to one-time review of protocols, to standing scientific advisory panels which have an ongoing role in the design and execution of the studies. Ongoing external review has proved beneficial to several of the studies.
- Public advisory committees might improve communications with the veterans asked to participate in epidemiologic studies.
- A single coordinating body with an overarching perspective is needed to monitor whether priorities are being established, whether outstanding research questions are being adequately addressed, whether individual studies will contribute to the overall effort, and the extent to which the studies are responsive to recommendations from external reviewers.
- Sharing a subset of basic questions on demographics, symptoms, and exposures across large surveys of Gulf War veterans and controls could provide information useful for comparisons across the studies and better understanding of differences in the study populations.
- There is little exposure data available for Gulf War veterans about many key risk factors. As a consequence, it will be more difficult to link adverse health outcomes detected by epidemiologic studies to some specific exposures or risk factors.
- The Persian Gulf Registry of Unit Locations data from DOD will be important for investigating questions about Gulf War veterans' health issues, but it will not be a substitute for missing exposure data for many risk factors.

RECOMMENDATIONS

- All epidemiologic studies aimed at Gulf War veterans' health issues should incorporate external scientific review and ongoing interaction with appropriate outside experts throughout the study process, from study design through analysis of results.
- The Persian Gulf Veterans Coordinating Board should play an active role in allocating the limited resources available for research on Gulf War veterans' illnesses. The Research Working Group of the Coordinating Board should monitor the findings

and recommendations of scientific peer review committees. If scientific reviews draw into question the usefulness of particular studies to the overall research strategy, the Research Working Group should, via the Coordinating Board, recommend appropriate actions to the Secretaries of the three departments involved.

- DOD, DHHS, and VA should recommend their principal investigators use public advisory committees in designing and executing epidemiologic studies of Gulf War veterans' illnesses.
- For those questions that are common to different surveys, coordination between principal investigators and survey design experts should take place to arrive at a common wording. The Persian Gulf Veterans Coordinating Board's Research Working Group should take responsibility for this coordination.
- The Persian Gulf Registry of Unit Locations should be made available to qualified government and private researchers as quickly as possible, within the constraints of confidentiality.
- DOD should make reasonable and practical efforts to collect and record better troop exposure data during future conflicts and to make those data available as quickly as possible to health care researchers.

Table 1—Epidemiology Studies Reviewed by the Advisory Committee, December 1995

Study	Description
National Health Survey of Persian Gulf Veterans and Their Family Members (Environmental Epidemiology Service, VA)	Postal survey to estimate the prevalence of symptoms and medical conditions in 15,000 Gulf veterans and 15,000 era veterans and their families (surveys mailed Fall 1995, preliminary report anticipated Fall 1996)
A Mortality Follow-up Study of Persian Gulf Veterans (Environmental Epidemiology Service, VA)	Comparison of mortality rates and causes in Gulf War veterans and era veterans (ongoing; preliminary results presented Fall 1995)
Study of Unexplained Illness Among Persian Gulf War Veterans in an Air National Guard Unit (National Center for Infectious Disease, CDC)	Three-phase study to verify and characterize symptoms, assess their prevalence, and investigate risk factors in an Air National Guard unit (two phases complete, final phase ongoing)
Health Assessment of Persian Gulf War Veterans from Iowa (Iowa Department of Health and National Center for Environmental Health, CDC)	Telephone survey to estimate the prevalence of symptoms and medical conditions in 1,500 Gulf veterans and 1,500 era veterans from Iowa and their families (telephone interviews begun Fall 1995, initial report anticipated August 1996)
A Study of Symptoms in Seabees (Naval Health Research Center, DOD)	Survey of symptoms in 1,500 Seabee volunteers (preliminary results presented Fall 1995)
Seabee Health Study (Naval Health Research Center, DOD)	Postal survey of 17,000 Seabees to assess symptoms and exposures (planning stages)
A Comparative Study of Hospitalizations Among Active Duty Military Personnel Who Participated in the Gulf War and Similar Military Personnel Who Did Not Participate (Naval Health Research Center, DOD)	Comparison of hospitalizations between active duty Gulf War veterans and era veterans who attended military hospitals (preliminary results presented Fall 1995)
A Comparison of Federal and Non-Federal Hospitalization Rates Among Veterans Who Have Separated From Active Service: Gulf War Veterans Versus Non-Gulf Veterans (Naval Health Research Center, DOD)	Comparison of hospitalizations between Gulf War veterans and era veterans who have separated from the military and attended non-military hospitals (planning stages)
A Comparative Study of Pregnancy Outcomes Among Gulf War Veterans (Male and Female) and Other Active Duty Personnel (Naval Health Research Center, DOD)	Comparison of birth defect rates between active duty Gulf War veterans and era veterans who attended military hospitals, using hospital records to ascertain birth defects (preliminary results presented Fall 1995)
Reproductive Outcomes Study (Naval Health Research Center, DOD)	Postal survey to compare reproductive outcomes in Gulf War and era veteran couples (ongoing)
Prevalence of Congenital Anomalies Among Children Born to Gulf War Veterans (Naval Health Research Center, DOD)	Comparison of birth defect rates between Gulf War veterans and era veterans, using state registries to ascertain birth defects (pilot test ongoing)

SOURCE: Presidential Advisory Committee, 1996.

Chapter 5

Chemical and Biological Weapons

The issues of whether U.S. troops were exposed to Iraqi chemical and biological warfare (CBW) agents during the Gulf War, and if so, whether such exposures can be causally linked to veterans' illnesses, remain a source of considerable controversy. The charter requires the Committee to take a fresh look at these issues. For the interim report, we have focused on Iraqi CBW capabilities and doctrine during the Gulf War (with an emphasis on new information uncovered by the United Nations Special Commission on Iraq) and CBW detection systems deployed in the Gulf.

BACKGROUND

A 1994 congressional report concluded, based on eyewitness accounts and declassified operational logs, that CBW agent exposures did occur.¹¹ Two other studies reached the opposite conclusion. The DSB Task Force stated it found "no evidence that either chemical or biological warfare was deployed at any level against us, or that there were any exposures of U.S. service members to chemical or biological warfare agents in Kuwait or Saudi Arabia."³ Similarly, an IOM panel found "absolutely no reliable intelligence, and no medical or biological justification for any of [the] reported claims" of CBW exposures.⁶ The NIH Technology Assessment Workshop Panel was less categorical, stating that "until it can be unequivocally established that chemical and/or biological weapons were not used and that troops were not exposed to plumes of destroyed stockpiles, the possibility remains that some symptoms are chronic manifestations of such exposure."⁴ In light of these findings, the Persian Gulf Veterans Coordinating Board determined that "although further DOD investigations of individual exposure reports may be necessary, further research is unwarranted unless creditable data establish that exposure to CBW agents actually occurred."¹²

Iraqi CBW Capabilities and Doctrine

The primary source of information on Iraq's CBW programs released since this Committee was established is the United Nations Special Commission on Iraq (UNSCOM), an international body charged with uncovering and eliminating Iraq's weapons of mass destruction and associated production facilities. Although the Iraqi government deceived UNSCOM for four years

about the full extent of its CBW programs, the defection to Jordan on August 7, 1995, of Lt. Gen. Hussein Kamel al-Majid, a son-in-law of Iraqi President Saddam Hussein and former director of Iraq's weapons programs, proved to be a major breakthrough in the investigation. After the defection, the Iraqi government handed over to UNSCOM nearly 680,000 pages of documents on Iraq's pre-war weapons programs, including CBW activities. UNSCOM cautions that much of the information contained in Iraq's most recent declarations remains to be fully verified, but recent revelations shed new light on Iraq's CBW capabilities and doctrine.¹³

UNSCOM Findings Regarding Chemical Weapons. In its October 1995 report, UNSCOM expressed greatest concern over new revelations about the timing, extent, and success of Iraq's VX nerve agent production program. New evidence suggests the VX program began as early as May 1985 and continued without interruption until December 1990. UNSCOM concluded that as much as 400 tons of VX could have been produced on an industrial scale and that Iraq had solved precursor and agent storage and stabilization problems. UNSCOM revealed that a 1989 Iraqi document on VX proposed "the creation of strategic storage of the substance so it can be used at any time if needed."

UNSCOM also noted Iraq's admission of the development of prototypes of binary sarin (nerve agent)-filled artillery shells, 122 mm rockets, and aerial bombs and observed that the newest documentation shows production in quantities well beyond prototype levels. Iraq also has admitted three flight tests of long-range missiles with chemical warheads, including one with the sarin in April 1990.

UNSCOM Findings Regarding Biological Weapons. Iraq's biological warfare (BW) program, as reported to UNSCOM, embraced a comprehensive range of agents and munitions. During the late-1980s, Iraq carried out scale-up studies on the production of anthrax and botulinum toxin, and these agents were weaponized in advance of the Gulf War. In addition, Iraq conducted research on a variety of other agents, including:

- *Clostridium perfringens*, a bacterium that causes gas gangrene in wounds;
- aflatoxin, which can cause liver cancer as well as acute toxicity;
- two lethal fungal toxins known as trichothecene mycotoxins;
- a plant fungus known as "wheat cover smut," a potential economic weapon against enemy crops;
- three nonlethal viral agents: hemorrhagic conjunctivitis (which causes an acute eye disease associated with intense pain and temporary blindness); rotavirus (which causes acute diarrhea that can lead to dehydration and death), and camel pox (which causes fever and skin rash in camels; infection in humans is rare); and
- two lethal viruses, yellow fever and Crimean-Congo hemorrhagic fever virus.

In its October 1995 report, UNSCOM expressed greatest concern over new revelations about the timing, extent, and success of Iraq's VX nerve agent production program.

After the invasion of Kuwait on August 2, 1990, the Iraqi BW program intensified dramatically. Emphasis shifted from development work to large-scale production and weaponization of BW agents. Iraq now claims it had BW bombs and missiles deployed at four air bases around the country ready for launch; these claims have not been verified.

UNSCOM Findings Regarding Iraqi CBW Doctrine. UNSCOM noted Iraqi authorities have made conflicting representations about their plans with regard to the operational use of CBW agents. Documentation now available supports the contention that Iraq was actively planning to deploy its chemical weapons in a pattern corresponding to strategic and offensive use through surprise attack. Although UNSCOM found that the known pattern of deployment of long-range missiles supports this contention, it continues to investigate whether Iraq intended first-use or only second-use of CBW.

Nothing in recent UNSCOM reports has caused DOD to reverse its position that there was no widespread use of CBW agents in the Gulf War. In the past few months, however, DOD has shown a new willingness to reexamine the issue. In Spring 1995, DOD created the Persian Gulf Investigation Team (PGIT), under the direction and control of the Assistant Secretary of Defense (Health Affairs), to conduct additional analytical work in this area. Part of PGIT's mandate is to investigate possible exposures to CBW agents during the Gulf War by drawing on all sources of information, including eyewitness incidents reported to a toll-free number and the full range of operational and intelligence records. During the Committee's October 1995 meeting, a PGIT official testified that the team was planning to investigate CBW issues fully.

In parallel with PGIT's investigation, the Central Intelligence Agency's (CIA) Office of Weapons Technology and Proliferation in the Directorate of Intelligence is conducting an independent review of intelligence documents to determine whether the agency's previous conclusions that U.S. troops were not exposed to CBW agents during the Gulf War still stand in the light of new information. The CIA has concentrated its review on intelligence records and limited its assessment of operational records and eyewitness accounts. CIA coordinates its activity with PGIT.

CBW Detection Systems Deployed in the Gulf

The United States deployed several types of chemical agent detectors in the Gulf War as part of an integrated system for dealing with possible chemical warfare (CW). Each service member had access to treated papers (M8 and M9) that are sensitive to droplets of liquid chemical agents. Units responsible for fresh water handling used the M272 Kit to detect the presence of chemical agents in water. Germany provided 60 FOX Reconnaissance Systems, sophisticated armored vehicles equipped with mass spectrometers for identification of chemical contamination. Approximately 45,000 M256A1 Chemical Agent Detector Kits were provided for use by trained personnel after a unit entered full protective posture to determine if a hazard actually existed.

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The M8A1 automatic chemical agent alarm was the primary U.S. system designed to provide early warning of chemical attack during the Gulf War. It suffered from a number of serious deficiencies. For example, it could not detect mustard agents, which Iraq was known to possess in large quantities. In addition, the M8A1 detector had an extremely high false-alarm rate. During the Gulf War, the alarms sounded in response to vehicle exhaust, smoke, dust, rocket propellant, and other common battlefield interferents, and also sounded in response to low battery levels and routine daily maintenance.

All CW agent detection and warning systems deployed in Southwest Asia were designed to detect nerve agent concentrations that would have an immediate impact on troop functioning—i.e., levels that would cause death or acute symptoms. No attempt was made to monitor CW agent exposures at levels below those known to cause acute toxicity. Battlefield detectors could not measure the types of low-level exposure that DOD regulations guard against in nonbattlefield situations.

No real-time biological warfare (BW) agent detection systems were deployed during the Gulf War. Britain, Canada, France, and the United States all deployed air samplers that collected and concentrated aerosol particles into a liquid sample suitable for testing with a small antibody based enzymatic test kit. This rudimentary detection system took several hours to produce a result and could only determine retrospectively if a biological attack had taken place.

DOD is taking action to address deficiencies in detectors that were highlighted by the Gulf conflict. If it works according to specifications, the detector/alarm currently under development, known as the Advanced Chemical Agent Detector/Alarm (ACADA), will be capable of detecting mustard agents, will identify the category or type of agent detected, and will not false alarm or malfunction during or after exposure to commonly occurring battlefield interferents. The response time of the ACADA at the detection threshold also will be shorter than the M8A1, reducing the risk of acute exposure.

DOD has not addressed the issue of monitoring low-level exposures to CW agents. The joint-service requirements document for the ACADA system notes that “the current automatic chemical agent alarm (M8A1) is not sufficiently sensitive to adequately monitor collective protection shelters for detecting sustained low levels of chemical agent and monitoring personnel for contamination.” Yet the ACADA system will have the same nerve agent detection threshold as the M8A1 it will replace.

To improve its capability to detect BW exposure, DOD currently is developing BW agent detection systems. However, systems that will provide real-time warnings that would enable troops to take protective measures prior to exposure are a long way off.

No real-time biological warfare agent detection systems were deployed during the Gulf War. Systems that will provide real-time warnings that would enable troops to take protective measures prior to exposure are a long way off.

FINDINGS

- Although much was known at the time of the Gulf War, UNSCOM's work provides a more definitive picture of Iraq's CBW capability and doctrine, revealing advanced capabilities and underscoring the considerable uncertainty regarding Iraq's intentions to use CBW agents against American and coalition troops.
- The U.S. government's decision to reexamine the records of the Gulf War for evidence of exposure to CBW agents is prudent in light of the health concerns of veterans and the findings from UNSCOM's investigations. The Committee intends to monitor the investigations of PGIT and CIA.
- DOD is taking reasonable steps to improve battlefield CW agent detection capability by developing equipment that will detect mustard agent and that will not sound false alarms in response to common battlefield interferents.
- The inability to provide real-time detection of BW agents constitutes a serious deficiency in the U.S. chemical and biological defense posture.
- The ability to monitor low-levels of CW agents would improve the health care surveillance of U.S. troops.

RECOMMENDATIONS

- CIA and DOD should coordinate their analyses to ensure a comprehensive review of the complete record of the Gulf War. Each agency should make full and prompt disclosure of all findings.
- DOD should devote more attention to monitoring low-level (subacute) exposures to CW agents. One possible basis for such a system is the automated air-sampling system developed by the U.S. Army Edgewood Research, Development and Engineering Center for UNSCOM, which is using it to monitor emissions from Iraqi chemical plants. Another approach might be to modify the detection system that the U.S. Army uses to monitor for leaks at chemical weapons storage depots.
- DOD should continue to invest in the development of a biological point detector/alarm system that can detect and identify BW agent aerosols rapidly enough to enable troops to take protective measures before being exposed.

Chapter 6

The Next Ten Months

Over the next 10 months, the Committee will continue to address each of the elements of its charge. Throughout the remainder of our work, we will monitor the government's responsiveness to the recommendations of this and previous advisory bodies (Appendix E). We also will scrutinize how effectively government programs are coordinated among the departments and agencies with an interest in the health and well being of veterans.

OUTREACH

The Committee's final report will include additional evaluation of the government's outreach efforts to Gulf War veterans, their families, and communities, including DOD's AFIS and AFRTS, the department's survey of active duty troops, and education and counseling provided by DOD during clinical evaluations. The Committee will examine VA's Persian Gulf Health Days, active duty preseparation briefings on Gulf War veterans illness issues provided through VA's Transition Assistance Program, special programs for women veterans, and outreach to Spanish speaking people. We will review suggestions received from veteran service organizations for improving outreach to Gulf War veterans.

The Committee will continue to review carefully the content of the departments' outreach message and whether its level of complexity makes it accessible for their audiences. We will investigate how the departments evaluate their own outreach components and programs. Without evidence to indicate how well outreach efforts reach the target population and how much this population actually learns about the relevant issues, claims of outreach program effectiveness are unsubstantiated.

The outreach programs of both departments have improved over the last two years. It remains important to highlight the lessons learned in implementing them in order to create a useful model of communication and outreach that would be responsive to veterans of future conflicts. The final report will explore this issue.

MEDICAL AND CLINICAL ISSUES

For the final report, the Committee intends to evaluate the quality of care provided to Gulf War veterans who enlist in VA's Persian Gulf Registry or DOD's CCEP. We will assess access to the treatment programs, the treatment protocols, the implementation of those protocols, and the attitudes of the health-care providers employed by the systems. In undertaking this evaluation, we will continue to receive public testimony, make site visits to VA and DOD medical facilities where the clinical evaluations are conducted, and interview veterans to assess their impressions of their access to care and their expectations from the registry protocols.

The Committee will conduct a review of clinical syndromes that might be similar to some of the undiagnosed illnesses among Gulf War veterans. We will assess the reproductive problems experienced by veterans and their families, including birth defects and decreased fertility. We also plan to examine the psychological sequelae of stress, which many previous advisory groups have identified as a high priority for the government's research program.

The activities of FDA and DOD related to the use of drugs and biologics intended to protect against CBW remain an area of considerable interest to the Committee. In particular, we plan to explore with FDA possible alternatives to the interim final rule to help ensure troops are protected against CBW. Some observers have suggested an approval standard that recognizes surrogate endpoints and other data indicative of efficacy for vaccines, drugs, devices, and antibiotics intended for CBW defense might be a more appropriate policy than a waiver of informed consent.

Previous advisory groups have made recommendations concerning health care for Gulf War veterans. For instance, the NIH panel⁴ recommended that a coordinated VA and DOD hospital-based case assessment protocol be developed to provide uniformly thorough assessment, diagnosis, and treatment; we believe a coordinated clinical protocol is now in place. The NIH panel also stated that clinical treatment, absent a proven etiology, must be managed on a case-by-case basis according to the symptoms presented. The Committee will continue to monitor the adequacy of the government's response to that recommendation (i.e., the quality of medical care provided to ill Gulf War veterans) during the remainder of our work. The IOM⁵ has been evaluating the CCEP since its inception, and we will follow DOD's response to IOM's continuing findings and recommendations with interest, but we will not try to duplicate its effort.

RESEARCH

The Committee will continue its review of research related to Gulf War veterans' illnesses. In particular, we will focus on the smaller epidemiologic studies and toxicologic research protocols designed to assess specific risk factors. In reviewing research directed at Gulf War veterans' health issues, the Committee will attempt to evaluate the overall research effort, identifying areas where key research may be missing or where additional efforts to investigate or coordinate could improve the understanding of Gulf War veterans' illnesses. The Committee intends to monitor research awards resulting from recently issued requests for proposals in order to evaluate the performance of the Coordinating Board.

Another source of information about the exposures and risk factors of the Gulf War is DOD's approach to occupational safety and health evaluations. The Committee believes reviewing the process by which DOD assessed potential exposures and risk factors before the Gulf War and the data DOD accumulated to support its decisions will be important for both evaluating Gulf War exposure and risk factors and anticipating future health issues. Data from pesticide applicators, uranium miners and fabricators, and firefighters, for example, exist and can be brought to bear in considering hazards that U.S. troops faced in Southwest Asia. For this avenue of inquiry, the Committee intends to focus on the question: How did DOD evaluate known risk factors when it approved materials for use in the Gulf?

CHEMICAL AND BIOLOGICAL WARFARE

In the coming months, the Committee will shift its focus from questions involving Iraqi CBW capabilities and the detection systems deployed by U.S. forces in the Gulf, to those involving alleged incidents of exposure to CBW agents. In particular, the Committee plans to examine instances where there are allegations that U.S. personnel were directly exposed to CBW agents, and to review evidence relating to possible collateral exposures to such agents. In addition, we plan to examine questions surrounding possible low-level exposures to CBW agents, including their potential medical effects. As part of this effort, the Committee plans to monitor closely the progress of DOD and CIA in their renewed investigations of possible CBW exposures during the Gulf War. Finally, the Committee will continue its review of developments relating to Iraqi CBW capabilities and the detection systems deployed by U.S. forces in the Kuwaiti Theater of Operations.

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List of Acronyms

ACADA	-Advanced Chemical Agent Detector/Alarm
AFIS	-American Forces Information Service
AFRTS	-Armed Forces Radio and Television Service
BT	-botulinum toxoid
BW	-biological warfare
CBW	-chemical and biological warfare
CCEP	-Comprehensive Clinical Evaluation Program
CDC	-Centers for Disease Control and Prevention
CentCom	-Central Command
CIA	-Central Intelligence Agency
CW	-chemical warfare
DHHS	-Department of Health and Human Services
DMDC	-Defense Manpower Data Center
DOD	-Department of Defense
DSB	-Defense Science Board
DU	-depleted uranium
ESG	-Environmental Support Group
FDA	-Food and Drug Administration
GAO	-General Accounting Office
IIRs	-Intelligence Information Reports
IND	-investigational new drug
IOM	-Institute of Medicine
IRB	-institutional review board
NIH	-National Institutes of Health
OMB	-Office of Management and Budget
PB	-pyridostigmine bromide
PGIT	-Persian Gulf Investigation Team
PHS	-Public Health Service
PSAs	-public service announcements
UNSCOM	-United Nations Special Commission (on Iraq)
VA	-Department of Veterans Affairs
VBA	-Veterans Benefits Administration
VHA	-Veterans Health Administration

Appendix A — Executive Order 12961

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

May 26, 1995

EXECUTIVE ORDER

----- PRESIDENTIAL ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Establishment. (a) There is hereby established the Presidential Advisory Committee on Gulf War Veterans' Illnesses (the "Committee"). The Committee shall be composed of not more than 12 members to be appointed by the President. The members of the Committee shall have expertise relevant to the functions of the Committee and shall not be full-time officials or employees of the executive branch of the Federal Government. The Committee shall be subject to the Federal Advisory Committee Act, as amended, 5 U. S. C. App. 2.

(b) The President shall designate a Chairperson from among the members of the Committee.

Sec. 2. Functions. (a) The Committee shall report to the President through the Secretary of Defense, the Secretary of Veterans Affairs, and the Secretary of Health and Human Services.

(b) The Committee shall provide advice and recommendations based on its review of the following matters:

(1) Research: epidemiological, clinical, and other research concerning Gulf War veterans' illnesses.

(2) Coordinating Efforts: the activities of the Persian Gulf Veterans Coordinating Board, including the Research Coordinating Council, the Clinical Working Group, and the Disability and Compensation Working Group.

(3) Medical Treatment: medical examinations and treatment in connection with Gulf War veterans' illnesses, including the Comprehensive Clinical Evaluation Program and the Persian Gulf Registry Medical Examination Program.

(4) Outreach: government-sponsored outreach efforts such as hotlines and newsletters related to Gulf War veterans' illnesses.

(5) External Reviews: the steps taken to implement recommendations in external reviews by the Institute of Medicine's Committee to Review the Health Consequences of Service During the Persian Gulf War, the Defense Science Board Task Force on Persian Gulf War Health Effects, the National Institutes of Health Technology Assessment Workshop on the Persian Gulf Experience and Health, the Persian Gulf Expert Scientific Committee, and other bodies.

(6) Risk Factors: the possible risks associated with service in the Persian Gulf Conflict in general and, specifically, with prophylactic drugs and vaccines, infectious diseases, environmental chemicals, radiation and toxic substances, smoke from oil well fires, depleted uranium, physical and psychological stress, and other factors applicable to the Persian Gulf Conflict.

(7) Chemical and Biological Weapons: information related to reports of the possible detection of chemical or biological weapons during the Persian Gulf Conflict.

(c) It shall not be a function of the Committee to conduct scientific research. The Committee shall review information and provide advice and recommendations on the activities undertaken related to the matters described in (b) above.

(d) It shall not be a function of the Committee to provide advice or recommendations on any legal liability of the Federal Government for any claims or potential claims against the Federal Government.

(e) As used herein, "Gulf War Veterans' Illnesses" means the symptoms and illnesses reported by United States uniformed services personnel who served in the Persian Gulf Conflict.

(f) The Committee shall submit an interim report within 6 months of the first meeting of the Committee and a final report by December 31, 1996, unless otherwise provided by the President.

Sec. 3. Administration. (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide the Committee with such information as it may require for purposes of carrying out its functions.

(b) Members of the Committee shall be compensated in accordance with Federal law. Committee members may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the Government service (5 U.S.C. 5701-5707).

(c) To the extent permitted by law, and subject to the availability of appropriations, the Department of Defense shall provide the Committee with such funds as may be necessary for the performance of its functions.

Sec. 4. General Provisions. (a) Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to the Committee, except that of reporting annually to the Congress, shall be performed by the Secretary of Defense, in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) The Committee shall terminate 30 day after submitting its final report.

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

WILLIAM J. CLINTON

THE WHITE HOUSE
May 26, 1995.

#

Appendix B — Advisory Committee Charter

CHARTER OF THE PRESIDENTIAL ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES

A. COMMITTEE'S OFFICIAL DESIGNATION: Presidential Advisory Committee on Gulf War Veterans' Illnesses ("Committee").

B. AUTHORITY: Executive Order No. 12961.

C. OBJECTIVES, SCOPE OF ACTIVITIES, AND DESCRIPTION OF DUTIES FOR WHICH THE COMMITTEE IS RESPONSIBLE: The duties of the Committee are solely advisory. The Committee shall provide to the President, through the Secretary of Defense, the Secretary of Health and Human Services, and the Secretary of Veterans Affairs, advice and recommendations based on its review of the following matters:

1. Research: epidemiological, clinical and other research concerning Gulf War veterans' illnesses.

2. Coordinating efforts: the activities of the Persian Gulf Veterans Coordinating Board, including the Research Coordinating Council, the Clinical Working Group, and the Disability and Compensation Working Group.

3. Medical treatment: medical examinations and treatment in connection with Gulf War veterans' illnesses, including the Comprehensive Clinical Evaluation Program and the Persian Gulf Registry Medical Examination Program.

4. Outreach: government-sponsored outreach efforts such as hotlines and newsletters relating to Gulf War veterans' illnesses.

5. External reviews: the steps taken to implement recommendations in external reviews by the Institute of Medicine's Committee to Review the Health Consequences of Service During the Persian Gulf War, the Defense Science Board Task Force on Persian Gulf War Health Effects, the National Institutes of Health Technology Assessment Workshop on the Persian Gulf Experience and Health, the Persian Gulf Expert Scientific Committee, and other bodies.

6. Risk factors: the possible risks associated with service in the Persian Gulf Conflict in general and, specifically, with prophylactic drugs and vaccines, infectious diseases, environmental chemicals, radiation and toxic substances, smoke from oil well fires, depleted uranium, physical and psychological stress, and other factors applicable to the Persian Gulf Conflict.

7. Chemical and Biological Weapons: information related to reports of the possible detection of chemical or biological weapons during the Persian Gulf Conflict.

It shall not be a function of the Committee to conduct independent scientific research. The Committee shall review information and provide advice and recommendations on the activities undertaken related to the matters described above. It shall not be a function of the Committee to provide advice or recommendations on any legal liability of the Federal Government for any claims or potential claims against the Federal Government. As used herein, "Gulf War Veterans' Illnesses" means the symptoms and illnesses reported by United States uniformed services personnel who served in the Persian Gulf Conflict.

D. OFFICIAL TO WHOM THE COMMITTEE REPORTS: The Committee shall report to the President through the Secretary of Defense, Secretary of Health and Human Services, and Secretary of Veterans Affairs. The Committee shall submit an interim report within six months of the first meeting of the Committee and a final report by December 31, 1996, unless otherwise provided by the President.

E. DURATION AND TERMINATION DATE: The Committee shall terminate thirty days after submitting its final report.

F. AGENCY RESPONSIBLE FOR PROVIDING NECESSARY SUPPORT: Financial and administrative support shall be provided by the Department of Defense.

G. MEMBERSHIP: The President shall appoint up to a maximum of twelve (12) members. Committee members shall have expertise relevant to the functions of the Committee and shall not be full-time officials or employees of the executive branch of the Federal Government. Committee members shall be compensated in accordance with federal law. Committee members may be allowed

travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. 5701-5707).

H. ESTIMATED ANNUAL OPERATING COSTS AND STAFF SUPPORT YEARS: It is estimated that the total annual costs of operations will not exceed \$3.5 million. Full time equivalent staff support years are expected to be approximately 30 years of effort.

I. NUMBER OF MEETINGS: The Committee shall meet as it deems necessary to complete its functions.

J. SUBCOMMITTEE(S): To facilitate functioning of the Committee, subcommittee(s) may be formed. The objectives of the subcommittee(s) are to provide advice and recommendations to the Committee with respect to matters related to the duties of the Committee. Subcommittees shall meet as the Committee deems appropriate.

K. CHAIRPERSON: The President shall designate a Chairperson from among the members of the Committee.

L. DATE CHARTER FILED:

03 JUL 1995

Appendix C — Staff and Consultants

Executive Director

Robyn Y. Nishimi, Ph.D.

Deputy Director/Counsel

Holly L. Gwin, Esq.

Director of Public Affairs

Gary L. Caruso

Timothy E. Phillips, Esq.*

Research Staff

Kelley A. Brix, M.D., M.P.H. - Senior Policy Analyst

Mark A. Brown, Ph.D. - Senior Policy Analyst

Joseph S. Cassells, M.D., M.P.H. - Senior Advisor for Medical and Clinical Affairs

Miles W. Ewing - Special Assistant

Kathi E. Hanna, M.S., Ph.D. - Senior Advisor for Policy Implementation

Lois M. Joellenbeck, Dr.P.H. - Senior Policy Analyst

Michael E. Kowalok - Research Assistant and Coordinator, Subcommittee Affairs

John D. Longbrake - Research Assistant

Thomas C. McDaniels, Jr. - Policy Analyst

Joan P. Porter, M.P.H., D.P.A. - Senior Policy Analyst

Jonathan B. Tucker, Ph.D. - Senior Policy Analyst

James C. Turner, Esq. - Senior Policy Analyst

Administrative Staff

Carol A. Bock - Executive Assistant

Barbara A. Bradley - Conference and Travel Services/Technical Editor

Michael R. Brown - Administrative Services

Philip B. Jackson - Telecommunications and Computing Services

Barbara Ketchum - Administrative Secretary

Debra J. McCurry - Information and Reference Services

M. Cecile Parker - Administrative Officer

Linda S. Rayford - Desktop Publishing/Word Processing Specialist

Tracy C. Smith - Secretary

* August-December 1995

Appendix D — Advisory Committee Meetings

August 14-15, 1995
Washington, DC

October 18-19, 1995
Arlington, VA

December 4-5, 1995
San Diego, CA

January 31, 1996
Washington, DC

Clinical Issues Panel
September 18, 1995
Charlotte, NC

Epidemiologic Research Panel
November 7-8, 1995
San Francisco, CA

Use of Investigational Drugs and Vaccines Panel
January 12, 1996
Kansas City, MO

Appendix E — Recommendations Made by Previous External Review Bodies

NIH Technology Assessment Workshop (April 1994)ⁱ

Recommendations	Comments*
An evolving case definition might be more appropriately used in developing a research strategy.	p. 27
Other cohorts of veterans should be evaluated.	pp. 28-29
Establish a more accurate estimate of symptom prevalence.	p. 27
A coordinated VA and DOD hospital-based case assessment protocol should be developed to provide uniformly thorough assessment, diagnosis, and treatment.	p. 44
Symptom rates should be compared among population groups (e.g., deployed vs. nondeployed, case-controls).	pp. 28-29
DOD should develop plans for prompt collection of high-quality relevant data (including baseline data) at any time U.S. forces are deployed in the future.	pp. 24, 35

Defense Science Board Task Force on Persian Gulf War Health Effects (June 1994)ⁱⁱ

Recommendations	Comments*
DOD needs substantial improvements in pre- and postdeployment medical assessments and data handling. These must be coordinated with VA.	pp. 17, 23
Clinical treatment, absent a proven etiology, must be managed on a case-by-case basis, directed at the symptoms presented. Carefully controlled treatment protocols might assist in carving out specific syndromes from the broad range of symptoms noted.	p. 44

Institute of Medicine Committee on the DOD Persian Gulf Syndrome Comprehensive Clinical Evaluation Programⁱⁱⁱ

Recommendations in First Report (December 2, 1994)	Comments*
The current design of the CCEP represents a serious attempt on the part of DOD to evaluate and treat the health problems of military personnel who served in the Persian Gulf region. However, the research aims of CCEP are not stated explicitly, nor does there appear to be a concrete epidemiologic study plan.	p. 44
Need for balance and clear delineation of the clinical care and research functions of the CCEP, especially in light of the apparent use of the CCEP by patients to obtain timely high quality medical care, which would otherwise not be as readily accessible.	p. 44
Incorporate consideration of the prominence of stress and psychiatric disorders as diagnoses and/or contributing factors in the CCEP findings.	p. 44
Recognition of the division of labor and other resources between local medical treatment facilities and regional medical centers, and between phase I and phase II/III of the CCEP, in light of the large numbers of CCEP patients.	p. 44

Recommendations in Second Report (August 7, 1995)	Comments*
The fact that many CCEP patients receive several diagnoses should be emphasized more in the conclusions of the DOD report. It should be clarified that there are many different combinations of diagnoses among the 10,020 patients. DOD should provide greater detail on additional specific diagnoses, including the categories of infectious diseases, and respiratory, digestive, and nervous system disorders.	p. 44
The DOD report includes comparisons between symptoms and diagnoses in the CCEP population and in several other populations but provides no explicit reason for making these comparisons. The draft report implies that a research hypothesis is being tested, but does not state what the hypothesis is.	p. 44
The DOD report does not explicitly state that it is likely that at least a few CCEP patients have developed illnesses that are directly related to their Persian Gulf service. This is a serious omission.	p. 44
The DOD report concludes that "Based on the CCEP experience to date, there exists no clinical evidence for a new or unique illness or syndrome among Persian Gulf veterans." The reasoning for this statement is not well explained, and DOD states it as though it were self-evident.	p. 44
DOD should continue to release its analysis of the CCEP results on a periodic basis.	p. 44

***Institute of Medicine Committee on Health Consequences of Service During the Persian Gulf War
(1995)^{iv}***

Recommendations: Data and Databases	Comments*
The VA Persian Gulf Health Registry is not a population database and is not administered uniformly, therefore it cannot serve the purposes of research into the etiology or treatment of possible health problems. It should be limited and specific to gathering information to determine the types of conditions reported; there should be quality control and standardization; and the registry should not be promoted as a means to determine prevalence estimates. In addition, VA should improve publicity about the registry, standardize protocol in the referral centers, and improve the timeliness of data entry.	p. 7
The Army Geographical Information System model is the proper approach to understand the characteristics of the population at risk. However, the DOD registry needs to be completed as quickly and accurately as possible. The Secretaries of DOD and VA should develop a single service-connected health record for each present active duty and former service member.	pp. 33, 35
DOD should maintain its lists of those receiving anthrax and botulinum toxoid vaccines for the purpose of conducting studies on these cohorts.	p. 23
Recommendation: Coordination/Process	
Presently, the total number of undiagnosed conditions is unknown because the data either are insufficiently understood or available. The Persian Gulf Veterans Coordinating Board should actively coordinate all studies developed from new initiatives that receive federal funding.	p. 31, 34-35
Recommendation: Considerations of Study Design Needs	
To date, most studies of Gulf War veterans have been piecemeal. They are necessarily incomplete, they usually lack proper controls, they are hard to generalize, and they are subject to grave statistical problems, including low statistical power. VA and DOD should determine the specific research questions that need to be answered and should design epidemiologic studies accordingly. They should collaborate to obtain population-based and controlled data on symptom prevalence, health status, and diagnosed disease.	pp. 31, 34-35

* Page numbers refer to preceding text in this document. Recommendations concerning research on specific risk factors will be considered as we review additional research protocols in the next two months. Unless otherwise noted, this Committee will continue to monitor the government's response to each of these recommendations.

ⁱ National Institutes of Health Technology Assessment Workshop Statement, April 1994.

ⁱⁱ *Report of the Defense Science Board Task Force on Persian Gulf War Health Effects*, June 1994.

ⁱⁱⁱ Institute of Medicine, Committee on the DOD Persian Gulf Syndrome Comprehensive Clinical Evaluation Program, 1994, 1995.

^{iv} Institute of Medicine, Committee to Review the Health Consequences of Service During the Persian Gulf War, 1995.

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